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Report

to the President and the Congress

on

Health Hazards Associated with Alcohol and Methods to Inform the General Public of these Hazards

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U.S. Department of the Treasury

and

U.S. Department of Health and Human Services

November 1980

FOR IMMEDIATE RELEASE NOVEMBER 25, 1980

Office of the White House Press Secretary

THE WHITE HOUSE

The report to the President and Congress on Health Hazards Associated with Alcohol and Methods to Inform the General Public of These Hazards by the Departments of Treasury and Health and Human Services is a useful summary of the scientific evidence linking excessive alcohol consumption to some of our most serious public health problems. The report is particularly valuable because it focuses public attention on the extent and nature of the serious risks to unborn children associated with alcohol consumption by pregnant women.

As directed by Congress, the Departments have considered the advisability of requiring that alcoholic beverages carry labels warning of the dangers of alcohol misuse by the public generally and by pregnant women in particular. The Departments gave this issue thoughtful consideration, consulted authorities both inside and outside government, and recommended against such labels at this time.

As the memorandum transmitting this report to the President and Congress notes, the report's conclusions and recommendations regarding warning labels address only the question of labelling alcoholic beverages and reflect the specific opinions of the two Departments. The rationale for the conclusions and recommendations does not represent the position of the Administration on the general issue of health warning labels, which can be a useful and cost-effective means of informing the public about health hazards in appropriate situations. In many circumstances, such labels are preferable to other forms of government action, which might be more intrusive or more costly. Warning labels can be an effective adjunct to other private and public health education efforts.

The scientific section of the report indicates that excessive alcohol consumption during pregnancy is one of the leading causes of mental retardation and birth defects. It is of the utmost importance to alert women of child-bearing age to the risks associated with alcohol. The debate over when to use warning labels should not distract government, industry, and concerned citizens from the urgent need to inform the public about this serious public health problem.

# # #

(For further information, contact Bob Berenson of the Domestic Policy Staff - 456-2837.)

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Glossary

To the Congress and the President of the United States

We are pleased to submit this report on Health Hazards Associated with Alcohol and Methods to Inform the General Public of These Hazards, prepared by the Departments of Treasury and Health and Human Services in compliance with the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act Amendments of 1979 (P.L. 96-180). Section 19 of the Act states that the Departments of Treasury and Health and Human Services shall jointly submit a report to the President and the Congress on:

(1) the extent and nature of birth defects associated with alcohol consumption by pregnant women.

(2) the extent and nature of other health hazards associated with alcoholic beverages, and

(3) the actions which should be taken by the Federal Government under the Federal Alcohol Administration Act and the Federal Food, Drug, and Cosmetic Act with respect to informing the general public of such health hazards.

In order to meet the requirements of P.L. 96-180, the Departments pursued two courses. A thorough review of the scientific literature was undertaken to identify and summarize the findings regarding the effects of alcohol consumption on the human body. Second, the Departments made a significant effort to consult with individuals knowledgeable about the health hazards associated with alcohol and ways to inform the general public of these health hazards. To achieve this goal, a number of steps were taken.

1. Federal Register Notice. The Departments announced in the Federal Register on February 26, 1980, Notice No. 80-4 (Appendix A to the Report), that we wanted information relating to:

(1) Ongoing or recently completed studies on Fetal Alcohol Syndrome.

(2) Any current research data on health problems associated with alcoholic beverage consumption.

(3) Any current research data on health problems associated with food or drugs containing alcohol. (Example: cough syrup or food extracts).

(4) Current research data on health problems associated with alcohol consumption in conjunction with the use of drugs. (Example: analgesics, tranquilizers, etc.)

(5) Studies which measure the effectiveness of different approaches to alerting the public regarding health hazards associated with a product.

The Departments received 158 comments which have been reviewed and analyzed by staffs of both Departments. The preponderance of the comments (72 percent) addressed the warning label issue with a ratio of 10 to 1 opposed to labels.

Half of those in opposition to labels stated that wine or beer were especially inappropriate for carrying warning statements. Approximately ten percent offered current research data or reviewed current activities relevant to the report.

Comments were received from the general public (38 percent), the beverage alcohol industry including appreciation societies, consultants, and wine and food editors (27 percent), alcoholism and health constituencies (16 percent), researchers and medical associations (8 percent), health care providers (7 percent), State alcohol beverage commissions (2 percent), and communications experts (1 percent).

2. Formal Consultations. The Departments held nine formal consultations with leading medical experts, representatives of the alcohol beverage industry, communications specialists, experts from the fields of alcoholism and traffic safety, and other interested parties, such as consumer groups. As directed by Congress, the National Advisory Council on Alcohol Abuse and Alcoholism was consulted. In addition, comments were solicited from the Interagency Committee on Federal Activities for Alcohol Abuse and Alcoholism. High level officials and staffs from both the Departments of Treasury and Health and Human Services participated in these consultations. Appendix B lists the experts consulted.

3. Informal Consultations. In addition, staffs from both Departments had numerous informal consultations with additional experts and have met with representatives of Government agencies with expertise, such as the Department of Transportation, the Federal Trade Commission, the Federal Aviation Administration, and the Veterans Administration.

An interim report was submitted by the Departments on June 1, 1980. It contained a request for an extension in order to analyze and utilize materials collected from the consultations and comments submitted in response to the Federal Register Notice.

This Report reflects the opinions of the two Departments involved; it should not be considered the opinion of the Administration or of other government agencies or departments. Furthermore in its discussion of warning labels the Report deals only with the question of labeling alcoholic beverages, taking into account the unique history of alcohol regulations in the United States. Although experiences with other products were reviewed, in no way should the conclusions or views expressed in this report be read as precedent for decisions involving other products. We believe the decision to place a warning label on any product should be made in the context of the facts surrounding the particular products involved.

Sincerely,

Richard J. Davis
Assistant Secretary
(Enforcement and Operations)
Department of the Treasury

Julius B. Richmond, M.D.
Assistant Secretary for Health and
Surgeon General
Department of Health and Human Services

EXECUTIVE SUMMARY

This Report to the Congress and the President concerns alcohol-related health-hazards, including the Fetal Alcohol Syndrome (FAS), and actions to be taken by the federal government to inform the public of such hazards. It follows the form of the three-part statutory directive of Congress (P.L. 96-180) to the Departments of Treasury and Health and Human Services (HHS).

The summarized findings on alcohol-related health hazards are based on a broad range of sources and represent the state-of-the-art in scientific research at this time. Alcohol as referred to in this Report includes the alcohol contained in beer, wine, and distilled spirits. The recommendations on ways to inform the public of these hazards are also based on consultations with scientists and other experts, including several in communications, and on deliberations by Departmental officials and staff who reviewed the entire body of information and comment gathered during the study and consultation period.

Part I -- Birth Defects and Anomalies -- summarizes current knowledge about the Fetal Alcohol Syndrome (FAS), birth defects, and other alcohol related risks to unborn children and post-natal development.

Part II -- Other Health Hazards -- summarizes a range of physical, mental and emotional illnesses and disabilities associated with the misuse of alcohol including alcoholism, and other alcohol-related hazards, such as accidents.

Part III -- Informing the Public about Health Hazards -- summarizes current knowledge concerning the use and apparent effectiveness of various methods to provide the public with health information, including health warnings and labels. Both current and planned efforts by government, the alcoholic beverage industry and its Beverage Alcohol Information Council (BAIC), and private groups to inform the public about alcohol-related health hazards are presented, as are recommendations for future action.

References to studies on which this Report is based are included, as are several appendices that provide detailed background information, among them an analysis of the statutory authority of the government in the area of informing the public of health hazards.

The following is a digest of key portions of the Report, including a series of recommendations and actions proposed and planned by the Departments of Treasury and HHS.

Part I - Birth Defects and Anomalies

- Fetal Alcohol Syndrome (FAS) has been identified among some children of alcoholic women. It is characterized by central nervous system disorders, growth deficiencies, a specific cluster of facial abnormalities, and other malformations, particularly skeletal, urogenital, and cardiac. FAS is suspected to be one of the leading causes of birth defects associated with mental retardation.

- Heavy alcohol use is associated with birth anomalies and is independent of other variables, including smoking.

- Decreased birth weight, frequently associated with increased risk to the newborn, has been observed among the children of women averaging one ounce of absolute alcohol (two standard drinks) per day during pregnancy.

- In one study there is evidence of an association between consumption of two standard drinks a week and spontaneous abortion.

- Birth defects have been observed in the offspring of animals given alcohol in their diets. These studies were developed to simulate human alcohol consumption and to control for confounding factors.

- Some limitations exist in the data derived from major human studies undertaken to date. Further research utilizing improved alcoholism detection instruments and a wider range of socioeconomic groups is warranted. Also, among the important questions that remain to be answered are: what is the level of consumption which produces a risk of FAS and other adverse outcomes; the degree to which an individual's genetic make-up influences a dose-response relationship; the vulnerable periods for susceptibility; and effects of different patterns of consumption (e.g. binge drinking).

- It is not yet known whether fetal injury derived from alcohol abuse is a direct effect of alcohol on the fetus or an indirect effect mediated by altered maternal physiology. However, in the broadest scope, alcohol abuse appears to be a risk factor in adverse fetal outcome.

Part II -- Other Health Hazards

- Alcohol misuse has a potentially detrimental effect on the body from its point of entry at the mouth through the entire gastrointestinal tract and to related organs such as the liver and the pancreas. The liver is often seriously damaged by chronic alcoholism, the most common disorders being hepatitis and cirrhosis. Cirrhosis was the seventh leading cause of death in the United States in 1975.

- Alcohol abuse contributes to nutritional deficiency and has been suggested as the most common cause of vitamin and trace element deficiency in adults in the United States. Besides diminishing the general health, nutritional deficiencies contribute to such disorders as anemia, convulsions, small bowel dysfunction, and Wernicke's encephalopathy (a brain disorder).

- Central nervous system dysfunction has been estimated to be present in 50 to 70% of sober alcoholics entering treatment.

- Alcohol consumption inhibits the release of certain hormones. Excess consumption has been implicated in impotency in men and early onset of postmenopausal menstrual cessation in women.

- Recent evidence suggests that alcoholism may be related to a genetic as well as social and environmental influences predisposition which also play significant roles.

- There is an association between alcoholism and depression in both men and women. Alcoholics often have high levels of depression, and alcohol can increase depression.

- Compared to the general population, a disproportionately high number of people with drinking problems commit suicide. Approximately, one third of suicides involve alcohol. A propensity for suicide is thought to be associated with certain conditions, such as depression, anxiety, mood fluctuations, and a decreased ability to interact socially, which are related to alcohol abuse.

- Heavy alcohol consumption has been associated with a number of adverse effects on the cardiovascular system, including a specific deterioration of the heart muscle, diminished cardiac output, and decreased contractibility of the heart muscle. On the other hand, moderate alcohol consumption has been associated with lower rates of coronary heart disease than those observed for abstainers. Further research is warranted.

- Heavy consumption has been related to degeneration of skeletal muscle.

- Heavy drinking increases the risk of developing cancer of the tongue, mouth, oropharynx, hypopharynx, esophagus, larynx, and liver. In the United States these sites represent 6.1 to 9.1 percent of all cancers in the white population and 11.3 to 12.5 percent in the black population. Alcohol appears to interact with tobacco to increase the risk of cancer.

- Laboratory experiments have shown that body sway, a motor function, shows significant impairment at fairly low blood alcohol levels of 0.04%. This is less than half the level (0.10%) that most states require as evidence for driving under the influence of alcohol.

- Traffic deaths are the major cause of violent death in this country. One third of all traffic fatalities are alcohol related. Drinking by drivers also plays a greater role as the severity of the crash increases. Alcohol is especially involved in accidental death and injury among young people.

- A significant number of industrial accidents, drownings, burnings, and falls have been attributed to alcohol misuse.

- Alcohol is a central nervous system depressant. Chronic exposure can result in tolerance and physical dependence.

- Alcohol consumption can affect both the pharmacologic and therapeutic actions of prescription drugs, over-the-counter drugs, and illicit drugs. Alcohol-drug interactions are reported to be the second most frequent cause of drug related medical crises in the United States.

Part III - Informing the Public About Health Hazards

The Departments found that numerous information gaps and substantial misinformation relating to alcohol use exist among the American public. To bring about an increased level of public awareness, the Departments recommend:

1. Government, industry and private organizations should develop and conduct a broad-based, diverse and highly visible public

information campaign on alcohol-related health problems. To the extent possible, the combined campaign should be built upon a common strategy.

2. In consultation with government, industry should develop an effective slogan and/or logo, or a family of related slogans or logos, to lend verbal or visual identity to the elements of the campaign. Alcoholic beverage producers should voluntarily use the slogan and/or logo in consumer product information.

3. HHS will expand its current efforts to inform and educate the public regarding major alcohol-related health hazards; Treasury will continue its current efforts to inform and educate the public regarding effects of alcohol consumption during pregnancy and continue to work with industry to monitor and encourage the Beverage Alcohol Information Council's Fetal Alcohol Awareness Campaign.

4. HHS will work with the Department of Education, voluntary groups, State agencies and industry groups concerned with alcohol education to increase the use of model alcohol curricula on the local level.

5. HHS will develop a public information program aimed at women who are pregnant or plan to become pregnant with advice on how to protect the health of their children. This will include appropriate advice about the rules of alcohol use.

6. HHS will encourage the accurate portrayal of alcohol-related health hazards in the print and broadcast media.

7. Treasury, while recognizing the important efforts that some segments of the alcohol beverage industry have taken to control their advertising practices, will encourage other industry members to review the impact of their advertising practices on alcohol-related health hazards and revise their voluntary codes of advertising as appropriate. The question of whether the Congress should place additional restrictions on alcohol beverage advertising should continue to be considered.

8. HHS and Treasury will support the National Highway Traffic Safety Administration in its efforts to promote programs to discourage driving while under the influence of alcohol.

Providing Clearer Information on Alcohol Content

The Departments are convinced that public awareness and understanding would be enhanced if the alcoholic content were consistently and clearly indicated on

all domestic and imported alcoholic beverages. The consumer could then, at least, comparatively evaluate the products. The Departments therefore recommend that a uniform alcohol content statement be required for all alcoholic beverages, and that alternative measures of content be explored to determine the most useful.

1. Congress should amend the FAA Act to require malt beverages to be labeled to disclose the alcohol content as a percent by volume.

2. Require distilled spirits to be labeled for alcohol content as a percent by volume.

3. Congress should amend the FAA Act to require all wines to be labeled to disclose the alcohol content as a percent by volume.

Provide Information to the Public through Health Professionals

Health professionals should be a primary source of information about health hazards associated with alcohol. Yet, during the Departmental consultations, physicians confirmed that most lack training regarding health consequences of alcohol use and many are unaware of the recent research findings about the five major health hazards discussed in this Report. The lack of current information was particularly troublesome respecting fetal alcohol effects. The Departments recommend the following action:

1. The Surgeon General will issue an advisory on the major health problems discussed in this Report.

2. HHS will encourage states to require that health care and other appropriate professionals seeking State licenses and recertification demonstrate their knowledge of alcohol-related health hazards.

3. HHS will increase its support for development of curricula about the health consequences of alcohol consumption, and will encourage incorporation of such curricula into the basic professional education for physicians, nurses, pharmacists, social workers, and other health care delivery system professionals.

4. HHS will encourage the development of more sophisticated social and medical screening techniques to improve identification of individuals at high risk for alcohol-related health hazards.

5. FDA will intensify its efforts in reviewing and updating prescription and OTC drug labeling to inform the health care professional and patient about the potential of alcohol-drug interactions.

6. FDA will continue other informational activities.

HEALTH HAZARDS ASSOCIATED WITH ALCOHOL

PART I & II

INTRODUCTION

Alcohol continues to be an important component of modern society. Consumption of moderate amounts of alcohol by social drinkers has been related to increased positive feeling states (128,130) and to increased social interactions in institutionalized geriatric patients (193). There is, however, only limited and inconsistent support for the commonly-held notion that alcohol reduces stress or tension (33). Moderate alcohol consumption also has been associated with lower rates of coronary heart disease than those observed for abstainers (260,311). Any potential benefit, however, must be weighed against the attendant risks associated with increasing alcohol consumption, such as hypertension, stroke, and other health hazards discussed later in this report (22,37,140,146). Another traditional aspect of alcohol consumption is that associated with its medicinal use to provide symptomatic relief for pain, insomnia, anxiety, and a host of other physical and psychological problems (149). Today, however, other pharmacological agents are prescribed because of greater symptomatic specificity and/or therapeutic effectiveness. These findings highlight the need for concentrated research on both the beneficial and detrimental consequences that accompany alcohol consumption.

This report deals with the effects of alcohol regardless of whether it is consumed in the form of beer, wine, or distilled spirits. Alcoholic beverages are widely available in Western societies, but the kind of alcoholic beverage and quantity of alcohol consumed vary greatly from person to person reflecting individual preferences and social norms. U. S. survey data suggest that one third of the adult population consists of abstainers or of persons who seldom take a drink. Another third consists of people who have up to 3 drinks per week. The remaining third contains people who consume 4 or more drinks per week; a portion of these, possibly as many as a third, are problem drinkers or alcoholics (121). Conventionally, the latter problem drinker group is thought to be most at risk of sustaining adverse health consequences from alcohol use. Dose-response relationships, however, cannot be established rigorously for any given person since individual differences in genetic and other biological factors may make certain individuals predisposed to specific organ pathologies at various levels of consumption.

It has been estimated that there are approximately 10 million problem drinkers (including men and women suffering from alcoholism) in the nation's adult population (18 years and older) (315), and there are approximately 3 million problem drinkers among youth between 14 and 17 years (316). It is estimated that alcohol abuse and alcoholism cost the U. S. nearly $43 billion in 1975 (19).

The following text summarizes information on birth anomalies and other disease entities associated with the use of alcohol. Additionally, certain nondisease health risks have also been examined and tabulated, including alcohol-drug interactions, alcohol-related accidents, and suicides. Others, such as crime and family violence, have not been included in this report. Many of the diagnostic categories are those used in the Eighth Revision of the International Classification of Diseases (ICDA-8) adapted for use in the U. S. Disease categories not having an ICDA-8 code, such as Fetal Alcohol Syndrome

and central nervous system impairment, have been included as separate categories when a relationship to alcohol abuse has been clearly established by clinical research studies.

The overall organization used in this report is to define each health hazard, establish its relationship to alcohol use including mechanism whenever possible, and to provide estimates of the extent of alcohol involvement. Estimates on the extent of alcohol involvement were obtained from published scientific studies. The ranges of these estimates are often quite large, in part because of differing definitions of alcohol use and abuse, differing characteristics of groups studied, differing study methods (e.g., retrospective vs prospective), and because different disciplines use different techniques.

It has also been noted that many studies use self-reported estimates of consumption and consequently may underestimate or overestimate the actual amount consumed. Instances of both situations are known to occur and are presumed to reflect such factors as denial, desire to be accepted into a treatment or research program, or lack of familiarity with personal drinking pattern.

Alcohol use, abuse, alcoholism, chronic alcoholism, alcohol misuse, social drinking, and problem drinking are all generic terms that are used by various people in different ways. Some use these terms in a behavioral sense, while others define them medically or by actual levels of consumption. In the present document, we have used these terms in the definitional context of the cited data source.

It is important to note that much of the information in this document was obtained from studies which included only male subjects. It is only in recent years that investigations have been designed specifically to determine the acute and chronic effects of alcohol consumption on women.

References cited in Part III, a listing of experts consulted by NIAAA (incorporated in Appendix B), and a glossary of technical and scientific terms are included in the Appendices section.

PART I - BIRTH DEFECTS AND ANOMALIES

"The extent and nature of birth defects associated with alcohol consumption by pregnant women..."

Introduction

A pattern of birth defects noted among some children of alcoholic women has raised serious concern among scientists and health authorities in recent years and has prompted intensive research into the relationship between such defects and the consumption of alcoholic beverages by pregnant women. Although there is widespread agreement that alcohol consumption and birth defects or anomalies are linked, scientists are just beginning to determine precisely the processes by which such abnormalities occur.

In 1968, French investigators (155) reported morphologic, psychomotor, and mental abnormalities in 25 of 54 children of alcoholic mothers. In 1973, Jones and Smith (125) introduced the term Fetal Alcohol Syndrome (FAS) to label a unique pattern of aberrant growth and morphogenesis noted in eleven children of alcoholic mothers. Subsequently, many corroborating case reports have appeared in the literature (223,235).

On the basis of 245 reported cases, the principal and associated features of FAS were grouped into four categories (43):

1) Central Nervous System (CNS): The most common CNS dysfunctions (seen in greater than 80% of the patients) were mental retardation, microcephaly (abnormal smallness of the head), and irritability in infancy. Less frequent, but still noted in greater than 50% of the patients were poor coordination, hypotonia (reduced muscle tone), and hyperactivity in childhood.

2) Growth Deficiency: Prenatal and postnatal reduction in body length and weight below the third percentile occurred in greater than 80% of the cases.

3) Characteristic Cluster of Facial Abnormalities: Most frequent and characteristic are short palpebral fissures, a short upturned nose with a hypoplastic philtrum (underdevelopment of the ridge between the base of the nose and the upper lip), a sunken nasal bridge, epicanthal folds (folds on the inner aspect of the eyelids), a thin upper lip, hypoplastic maxilla (underdevelopment of the midface), and growth retardation of the jaw. These facial anomalies are individually subtle, but when jointly present, they characterize a face which is sufficiently distinctive to be recognized as FAS by trained dysmorphologists.

4) Other Major and Minor Malformations: Among the FAS patient population there is an increase in malformations of various organ systems including cardiac, urogenital, and skeletal. For example, skeletal defects include aberrant palmar creases, and limited joint movements, particularly of fingers and elbows.

Clinical presentations of birth defects and anomalies less severe than the FAS, such as low birth weight, abnormalities of the oral cavity and genitourinary systems, and altered behavioral patterns, have been reported (100,148, 206,268,274). These conditions in various permutations have been noted among the children of alcoholic women. Low birth weight and behavioral anomalies have been reported also in the children of women who drink at levels less than those associated with alcoholism; in these latter nonalcoholic women, there is a reported increased incidence of spontaneous abortion. The relationships of congenital abnormalities, growth retardation, behavioral/intellectual impairment, or developmental impairment to alcohol consumption have been assessed through epidemiological studies, which are discussed in the next section.

Human Studies

Although several hundred cases of FAS have been reported (6,43,56,178, 207), FAS has not been recorded to date in the children of other than alcoholic women. Since the diagnosis of maternal alcoholism is a consistently noted characteristic accompanying FAS, alcohol is considered the likely teratogenic or embryotoxic agent for these patients. However, alcoholics are also likely to be heavy smokers, use caffeine and other drugs, exhibit malnutrition, and lead a life style distinct from the nonalcoholic population. While each of these factors could therefore account for or contribute to the association noted clinically between alcohol and FAS, epidemiological studies and animal experimentation have implicated alcohol as the probable agent.

Epidemiological data also point to an alcohol-related increased incidence of congenital birth defects, birth anomalies, and altered development. In a medical record prospective cohort study conducted at a Cleveland medical center, Sokol et al. (268) analyzed 12,127 consecutive pregnancies over a 52-month period. Within this sample, 204 women (1.7%) were clinically diagnosed as alcoholic in the antepartum period. These alcoholic women did not differ from the remainder of the sample in racial distribution or parental education. For the alcoholics, a statistically significant increased risk was associated with alcohol consumption, but not with smoking, for a number of items among which were: history of habitual spontaneous abortion, history of low infant birth weight (below the 3rd percentile), need of antepartum nondelivery hospital admission, premature separation of the placenta, uterine tetany, heavy meconium, precipitous delivery, neonatal Apgar score below 7, neonatal infections, and abnormalities of the oral cavity and genitourinary systems. A sufficient number of alcoholics who were not cigarette users was present to permit an analysis of age-weight outcomes independently for alcohol and for cigarettes. Of the nonalcoholic non-smokers, 3.2% delivered small-for-gestation-age (SGA) infants, compared to 5.8% of the nonalcoholic smokers (relative risk 1.8), 7.8% of the alcoholic non-smokers (relative risk 2.4), and 12.4% of the alcoholic smokers (relative risk 3.9). Five infants, all from the alcoholic group, were diagnosed by the neonatologist as having FAS. Since this study had not been originally designed to investigate alcohol use during pregnancy, the actual number of identified alcoholics is probably markedly underestimated at 1.7%.

Another epidemiological study was conducted at Boston City Hospital with 633 pregnant women (206). Of these, based upon self reporting 9% were classified as heavy drinkers, defined as averaging more than 1.5 ounces of absolute alcohol per day, with five or more drinks on at least one occasion per month. Women who drank less than once a month were labeled as abstinent or rare drinkers (52%), and those women meeting neither rare nor heavy criteria were grouped into the moderate drinking category (39%).

After delivery, a physician administered a detailed pediatric, neurological, and developmental examination without prior knowledge of any history to 322 of the infants. Infants were classified as abnormal if they displayed congenital anomalies, growth abnormalities, or abnormalities on the neurological examination. Twice as many infants born to the heavy drinking women were found to be abnormal as compared to either moderate drinking or rare drinking/abstinent women (71% vs 35%); the finding of 35% abnormalities in the control group implies that the population served by Boston City Hospital is one generally at high risk. Additional comparisons between infants of heavy drinkers and those of the other groups revealed statistically significant differences in jitteriness (29% vs 10%), number of infants who were small-for-gestation-age (SGA) (27% vs 8%), birth length, birth weight, smaller head circumferences, microcephaly below 3rd percentile (12% vs 0.4%), congenital anomalies (32% vs 9 to 14%), major anomalies (17% vs 3%), and multiple congenital anomalies (20% vs 3 to 5%). Analysis of several other variables which may have affected outcome revealed inadequate diet in both the heavy drinkers and the control groups; also, fewer significant statistical relationships were observed when considering smoking rather than alcohol consumption.

The possibility that moderate and social drinking have adverse effects on fetal outcome has also been explored. A prospective study of 1,529 pregnancies at the University of Washington was initiated to address this issue. In one analysis of a subsample of this population (100), the children of women who reported consuming one or more ounces of absolute alcohol per day just prior to, or during pregnancy, or who experienced one or more episodes of heavy drinking in this period, were compared to children of light drinking and abstaining mothers with regard to growth and morphogenesis. The pediatrician evaluated infants by a standard examination without knowledge of maternal history. Particular attention was paid to: 1) gestation size, 2) possible microcephaly, 3) small palpebral fissures, and 4) combinations of specific dysmorphic features, such as broad low nasal bridge and long philtrum. Of 163 infants examined, 11 infants with clinical features of abnormal growth and morphogenesis were found, 9 from the index group and only 2 from the controls. Two of the 9 in the index group were diagnosed as FAS; however, their mothers were very heavy rather than moderate drinkers. Partial presentation of the syndrome occurred in a statistically significant manner, more frequently in the index cases than in the control group (7 vs 2). In 6 of the 7 index cases, alcohol intake, by self-report, was above one ounce but below two ounces of absolute alcohol per day.

Behavioral and neurological effects were assessed in additional analyses of subsamples from the Washington study. In one analysis, 417 neonates were examined on the Brazelton Behavioral Scale (274) and statistically significant effects of alcohol, distinct from smoking, caffeine, and other factors, were found on scores related to poor habituation, muscle tone, and decreased activity. Systematic naturalistic observations in another analysis (148)

revealed a number of neonatal behavioral patterns associated with increasing maternal alcohol consumption. These infant behaviors, atypical for healthy term babies, included: 1) increase in time spent with open eyes, 2) increase in body tremors, 3) increase in head-to-left preference, 4) decrease in the proportion of time spent in high levels of body activity, and 5) large increase in hand-to-face (self-stimulatory) activity.

Decreased birth weight has been used frequently as an index for increased neonatal risk (72,159). In a prospective study of 263 members of a health maintenance organization (168), a statistically significant decrease in infant birth weight of 91 grams was obtained for women who reported averaging one ounce of absolute alcohol per day for the pre-pregnancy period. The same amount ingested in late pregnancy was associated with a decrease in infant birth weight of 160 grams. These women had been carefully matched to controls for the contribution of smoking. In addition to smoking, the associations were independent of such variables as maternal age, height, parity, gestation age, and sex of the child. Kaminski et al. (129) have also reported a small but statistically significant decrease in birth weight, independent of smoking, for women who drank above 1.5 ounces of absolute alcohol per day during pregnancy.

Recently, two studies (101,142) have reported that spontaneous abortion is positively associated with alcohol consumption. In one study (142), an association was evident when one ounce of absolute alcohol was reported consumed twice per week. The other study (101) reported a statistically significant increased risk for second trimester spontaneous abortion at the level of 1 to 2 drinks (0.5 to 1 ounce of absolute alcohol) per day. Both studies controlled for likely confounding variables including smoking.

Animal Models

Animal models are used to determine alcohol's potential teratogenesis and the mechanisms which may produce any observed adverse effects. Animal models are also used to assess the effects of potential confounding variables such as nicotine, caffeine, and malnutrition. However, this strategy introduces a new complication since the physiologic and metabolic alterations produced by alcohol may be different from species to species, and from humans. Thus, the examination of many species is necessary for greatest validity.

The most appropriate animal studies, to date, have controlled for potentially confounding factors by: 1) avoiding alcohol administration via a route that may cause direct placental or fetal injury, 2) nutritional control (termed pair-fed control) in which the nonalcohol-treated control animals do not receive a more nutritious diet than animals consuming alcohol, and 3) monitoring of blood alcohol levels. This latter factor is required to ascertain that the blood alcohol levels are elevated to an extent comparable to human situations.

Chernoff (40) and Randall and co-workers (224,225) employed vitamin-fortified liquid diets containing alcohol and pair-fed controls and observed dose-related

effects of alcohol on prenatal mortality and frequency of malformations in mice. Many of the defects observed were similar to those reported in FAS patients, i.e., cardiac anomalies, hydronephrosis, limb defects, and microphthalmia. Similar findings have been reported in the beagle dog (66); in these canine studies the alcohol-treated dogs actually had a higher total caloric intake than the controls.

It is noted that rodents ingesting alcohol, even with an all liquid diet, decrease total food intake. Thus, in the pair-fed design, controls are restricted to the same extent. The importance of animal studies to date is that with nutrition-matched controls, significantly elevated teratogenesis is found in alcohol-fed animals.

Incidence

Incidence data have been obtained for certain regions of Europe. In Göteborg, Sweden (204) an incidence of 1/600 births for definite FAS with an equal number of probable FAS cases has been reported for the 7,600 births in that city over a recent 17-month period. A similar incidence was reported for Roubaix in the north of France based upon 6,927 total births in 1975 and 1976 (56). FAS data are not currently found in the large national data bases in the U. S. However, it has been reported in the literature, based upon clinical experience at certain American health centers, that FAS is one of the leading causes of birth defects frequently associated with mental retardation (43,263). The two most common birth defects associated with a significant incidence of mental impairment, Down's Syndrome and spina bifida, have been reported to occur in the U. S. at 1/1,332 and 1/2,012 respectively (287). Given the reported high incidence of FAS of 1/600 in two European studies (56,204), it is of importance to obtain accurate epidemiological estimates of incidence in the U. S.

It is clear that alcohol use is associated with a wider spectrum of congenital anomalies and growth abnormalities than just the FAS. The increased occurrence of such abnormalities is discussed above in an earlier section. Epidemiological data from the Cleveland (268) and Boston (206) studies indicated that heavy alcohol use substantially increased the risk for an adverse fetal outcome even when other potentially contributory variables were considered. Furthermore, a decrease in birth weight appears to be associated with more moderate alcohol ingestion (168).

Mechanisms

The actual mechanisms underlying the adverse effect of alcohol consumption on fetal and neonatal growth and development are unknown. It is plausible that the direct action of alcohol on the developing embryo may exert a toxic or teratogenic effect (28). Acetaldehyde, a metabolic product of alcohol, is

another possible agent. Alcohol abuse is also associated with a number of nutrient deficiencies, including the vitamins thiamin, folate, pyridoxine, and minerals such as zinc. In turn, deficiencies of such agents during even brief periods of pregnancy have been reported to be associated with teratogenesis (114). It is conceivable, therefore, that the embryotoxic and teratogenic effects derived from alcohol abuse in pregnancy may arise as a consequence of nutritional deficiencies.

Alcohol consumption during pregnancy has been considered as the likely antecedent of alcohol-related fetal anomalies. However, other mechanisms for teratogenic actions are plausible as well. Alcohol abuse prior to pregnancy may result in physiologic damage to reproductive organs, or in other metabolic or physiologic dysfunctions, which can persist beyond the alcohol abusing period (248). Hence, a fetus might conceivably be adversely affected even if the mother terminated abusive drinking before pregnancy. Moreover, damage by alcohol to gametes in the female or in the male are possibilities for genetic, as distinct from teratogenic, injury (9,139).

Support for the hypothesis that heavy alcohol consumption during the actual pregnancy period contributes substantially to the risk for adverse neonatal outcome is provided by the Boston City Hospital study (206) as well as a study in Sweden (204). In the Boston study, 15 of 42 heavy drinkers significantly reduced their alcohol intake during pregnancy. Ten of the 15 (67%) had normal babies while only 2 of 27 (7.4%) women who continued to drink heavily throughout pregnancy had infants considered to be normal.

Studies using low doses of alcohol may provide some indication of the mechanism(s) involved. The ingestion of small amounts of alcohol has been shown to affect fetal physiologic functioning in studies of fetal breathing movements. Consumption of one standard drink (0.5 ounce of absolute ethanol) significantly suppressed fetal breathing movements in two independent studies (75,161), indicating an acute alcohol effect at this dosage on the fetal central nervous system. The long-term consequences of this effect are not known.

Alcohol consumption during lactation and the consequent effects on nursing infants is also an area of concern. Heavy alcohol consumption is known to decrease milk ejection (44). This factor, coupled with the impaired sucking ability noted in some offspring of heavy alcohol consumers (43) would be expected to contribute to nutritional deprivation in the infant. Alcohol also readily enters the breast milk (20) thereby providing alcohol to the nursing infant. Alcohol derived by this mechanism has been attributed as the cause of a pseudo-Cushing's Syndrome in infants (20).

Conclusions

It is recognized that there are some limitations in the human studies undertaken to date. The population in the Boston City Hospital study was small and was predominantly derived from deprived socioeconomic groups.

The Cleveland study utilized a much larger population, but since this study had not been originally designed to investigate alcohol use during pregnancy, the prevalence of alcoholism was probably underestimated. Thus, while both studies indicated a significant risk for a congenital anomaly in pregnancy outcome with heavy alcohol use, e.g., 32% vs 9 to 14% for controls in the Boston study and 38% vs an expected 10% for a subsample of the Cleveland study, further research utilizing improved alcoholism detection instruments and a wider range of socioeconomic groups is warranted. It is not yet known whether injury derived from alcohol abuse is a direct effect of alcohol on the fetus or an indirect effect mediated by altered maternal physiology.

However, the extensive number of case reports on FAS and the studies of alcohol use during pregnancy, both in humans (56,204,206,268) and in animals (40,224,225), has led investigators to the reasonable assertion that alcohol abuse is a risk factor for fetal outcome. Whether the types of defects produced are sufficiently characteristic to be differentially labeled FAS has been questioned by some (188), but regardless of whether a label is applied or not, it appears that maternal alcohol abuse is related to adverse effects on fetal growth and development.

Many important questions remain to be answered including what are: 1) the dose-response relationships for fetal alcohol syndrome and other adverse outcomes associated with maternal alcohol consumption? 2) the degrees of inter-individual variability with respect to dose-response relationships? 3) the vulnerable periods for susceptibility to alcohol-associated birth defects and anomalies? and 4) the effects of different patterns of consumption (e.g., binge drinking)?

PART II - OTHER HEALTH HAZARDS

"The extent and nature of other health hazards associated with alcoholic beverages..."

Gastrointestinal System

Esophageal, Gastric, and Duodenal Effects

Esophageal lesions have been associated with abusive alcohol consumption and are manifested by local pain, difficulty in swallowing, and even the life-threatening complication of hemorrhage. In some chronic alcoholics, severe vomiting may result in mucosal tears at the gastroesophageal junction, the so-called Mallory-Weiss Syndrome (272). Acute motor dysfunctions of the esophagus, via interference with both sphincters and the peristaltic response to food ingestion also have been reported (109). Esophageal varices often develop in people with cirrhosis of the liver and can be eroded to the point of hemorrhage either by direct alcohol irritation or by upward movement of gastric contents (38).

Acute and chronic alcohol ingestion have been widely reported to be associated with a variety of inflammatory lesions of the stomach (42). Gastrointestinal bleeding from erosive gastritis and acute gastroduodenal ulcerations are common following acute alcoholic intake. The combination of alcohol and salicylates appears to be particularly dangerous (50,134). Chronic alcohol ingestion has been associated with an increased incidence of not only erosive but also atrophic gastritis (42).

Although the clinical and morphological sequelae of acute and chronic alcohol ingestion on the gastrointestinal tract are recognized, the mechanism of damage has not been conclusively established. It is known that alcohol directly or indirectly (59) stimulates acid secretion (80) which can irritate stomach linings. In addition, high concentrations of alcohol delay the evacuation of gastric contents thereby increasing irritation (12).

Digestive disturbances in the small intestine are common in alcoholics (191). In healthy volunteers and alcoholics the acute administration of alcohol appears to lead to changes in intestinal motility, whether given orally or intravenously (216,231). These alterations may contribute to the diarrhea frequently seen in binge drinking alcoholics (231). It is generally accepted that alcohol administration can lead to intestinal malabsorption, but there are differences in the effects on the absorption of individual compounds (see following section on "Nutritional Deficiency").

Pancreatitis

Long-term alcohol abuse is strongly associated with a significant incidence of chronic pancreatitis (13). Alcoholism may also be associated with subclinical pancreatic damage as demonstrated by pancreatic functional disturbances found in 29 of 54 alcoholics who did not display clinical symptoms of pancreatitis (85). Acute alcohol intoxication has been shown to interfere with pancreatic secretion of digestive enzymes (199,233), a finding which may account for some of the abnormalities in intestinal absorption associated with chronic alcoholism (192).

Alcohol may inhibit pancreatic secretion of digestive enzymes by a direct effect on the pancreas (180). Rats given alcohol chronically for periods of 14-53 weeks showed ultrastructural changes in pancreatic acinar cells similar to those found in liver cells after chronic heavy alcohol use (49). Alcohol ingestion also decreased pancreatic ATP content in rabbits, which is further evidence for a direct effect on secretory cells (269).

Although various surgical procedures have been attempted to relieve the symptoms of pancreatitis, the most reliable therapy appears to be abstinence from alcohol (13).

Liver Disease

The liver is the largest and most metabolically complex organ in the body. It is involved in the normal biological functions of circulation, excretion, immunology, metabolism, and detoxification. The liver is one of the organs most significantly affected as a result of alcohol ingestion. Alcohol consumption alters such liver functions as carbohydrate metabolism (117); conversion of amino acids into proteins such as albumin, transferrin, and complement; lipid metabolism (84); and detoxification or alteration of many chemical substances and drugs such as alcohol, acetaldehyde (164), anticoagulants, contraceptive pills, sedatives (133), and hormones (92). Because the liver is essential for the production, modification, and detoxification of so many important substances, damage to or alteration of its function can also result in deleterious secondary effects on other organs.

Alcohol-induced changes of lipid metabolism in hepatic cells can result in the reversible accumulation of lipid, mainly triglycerides, in the liver. This "fatty liver" condition has been regarded generally as a subclinical disorder (171), although concomitant liver failure and death have been reported also (132)..

Alcoholic hepatitis is a more serious condition than fatty liver and involves an inflammatory reaction of the liver, alteration in the structure and function of its cells, the presence of necrosis, appearance of alcoholic hyaline, and finally a diffuse fibrosis of the liver. Tissue lymphocytes may play an important role in the production as well as the progression of alcoholic hepatitis. About 45 percent of cases of alcoholic hepatitis show focal areas

where lymphocytes have infiltrated the liver. These lymphocytes can often be seen between liver cells, and also to be invading liver cells in what appears to be an immunologic allergic reaction to hyaline. It has been found that peripheral-blood lymphocytes from patients with alcoholic hepatitis respond to the presence of purified alcoholic hyaline by increased release of a substance called migration-inhibitory-factor (MIF) (153), thereby increasing the destruction of liver cells. Thus, it seems possible that certain types of lymphocytes (especially those known as thymus-derived lymphocytes or T-cells) may have a role in liver cell injury following alcohol ingestion, with more T-cells present in the liver and fewer in the peripheral blood (152). This immunologic phenomenon between alcoholic hyaline and lymphocytes may help to explain why long-term outlook and survival is not completely improved in patients abstaining from alcohol after they have developed alcoholic hepatitis, since progressive immunologic damage can continue even after alcohol withdrawal because hyaline bodies are still in the liver.

Cirrhosis is a chronic inflammatory disease of the liver in which functioning liver cells are replaced by scar tissue. Although alcoholic hepatitis may be a precursor to cirrhosis (237), it has been demonstrated that alcohol can produce fibrosis, and perhaps even cirrhosis, without any antecedent stage (220). One of the major questions which still needs to be resolved is the mechanism whereby alcohol ingestion leads to cirrhosis in humans. Although cirrhosis was once thought to result from poor nutrition, studies of baboons receiving alcohol and a nutritionally adequate diet suggest that heavy alcohol consumption can lead to cirrhosis in spite of an adequate dietary intake (166).

Cirrhosis accounted for 31,623 deaths in 1975 making it the seventh most common cause of death in the U. S. (289,317). Estimates of alcohol involvement ranged from 41 to 95% or 12,965 to 30,042 people (53).

Nutritional Deficiency

Heavy alcohol intake contributes to nutritional deficiency by disrupting physiologic and metabolic processes of digestion (163,170,259). Alcohol itself is highly caloric, supplying 7.1 kcal/gram. Thus, a consumer of 20 ounces of 86 proof distilled spirits derives 1,500 kilocalories, or over one-half of his or her daily caloric needs. The calories derived from alcohol have been termed "empty" (163) because of the small amounts of vitamins, minerals, essential amino acids, or essential fatty acids contained in most alcoholic beverages.

Primary malnutrition, resulting from a decrease in the actual ingestion of nutrients, is frequently associated with heavy alcohol use. Other factors also contribute to this kind of nutritional imbalance, for example, anorexia, vomiting, and diarrhea.

Secondary or conditioned malnutrition, i.e., deficient nutrient utilization, is commonly associated with alcohol abuse and has been related to alterations in all organs of the gastrointestinal tract (163,259); maldigestion and

malabsorption of nutrients, such as of the vitamins folate (99,108) and thiamin (112); and decreased activation or increased inactivation of nutrients as has been noted with vitamin B_6 (170).

Alcohol abuse has been suggested as the most common cause of vitamin and trace element deficiency in adults in the U. S. (98,151). Both inadequate intake and secondary factors, discussed above, are contributory. Such vitamin and nutritional deficiencies include folate (99,108), thiamin (112), vitamin B_6 (170), carnitine in alcoholic cirrhotics (238), vitamin A (264), and zinc (264). Other abnormal alterations are seen in magnesium (14) and phosphate (143) levels. Energy wastage, another factor contributing to malnutrition, has been documented among heavy users of alcohol (217).

The deficiency states derived from alcohol abuse are today more frequently marginal than overt (264), although overt disorders do appear, such as Wernicke's encephalopathy (thiamin deficiency). The alcohol-derived nutrition deficiency does, however, result in suboptimal health, and is contributory to the etiology of a number of abnormalities seen in alcoholics, such as anemia, convulsions, and small bowel malfunction.

Nervous System

Wernicke-Korsakoff Syndrome

Long-term alcoholism, especially when combined with malnutrition, often results in severe neurological and cognitive deficits. Some of the most severe and best documented effects are seen in the classical Wernicke-Korsakoff Syndrome (294). The major symptoms of the Wernicke stage of this illness appear acutely and include a global confusional state, ophthalmoplegia, nystagmus, ataxia, and polyneuropathy of the legs and arms. Neuropathological studies (294) have attributed these symptoms to alterations in neural structures within the cerebellum, brain stem, and diencephalon. If the patient with a Wernicke encephalopathy is not treated with large doses of thiamin, he/she is in danger of having fatal midbrain hemorrhages (294). If such a patient receives proper vitamin therapy, the neurologic symptoms will often show marked improvement. In most cases, the ocular problems will disappear, the ataxia and peripheral neuropathies will improve, and the confusional state will clear. The remaining clinical symptoms are those of the chronic Korsakoff stage of the Syndrome. It is important to note that very few Wernicke patients whose etiology involves alcohol abuse show a complete recovery to their premorbid cognitive state.

The neurotoxic effects of alcohol which can result from years of heavy consumption have been implicated in alcoholic Korsakoff patients. The most striking and persistent features of these people are severe amnesia, confabulation, and remarkable personality alterations (32). The Korsakoff patient's memory disorder involves both anterograde (difficulty in learning new information) and retrograde (difficulty in recalling public and personal events from the recent past) amnesias. In a seeming attempt to cope with these gaps

in memory, the Korsakoff patient confabulates or recites imaginary experiences. Regardless of premorbid personality characteristics, the Korsakoff patient is passive, indifferent, and lacking in affect and initiative. Given this combination of cognitive and personality symptoms, it is not surprising that almost all Korsakoff patients must be institutionalized for the remainder of their lives.

Approximately 1,800 short-stay hospital discharges (288,318) and 26 deaths were reported in 1975 for Wernicke-Korsakoff (289,317).

Peripheral Neuropathy

Alcoholic neuropathy is characterized by muscle weakness, diminished sensitivity to touch, pinprick, vibration, and paresthesia (burning or prickling sensation). These symptoms appear in a bilateral and symmetrical fashion, occurring initially in the distal portion of the lower extremities and occasionally affecting the upper extremities as well. Both sensory and motor nerves are affected.

It has been reported that approximately 70% of 150 alcoholics showed signs of myopathic and/or neuropathic disease (305). Subclinical evidence of peripheral nerve dysfunction was noted in 28 of 30 randomly selected alcoholics (154).

Underlying neuropathology has been described as interference with nerve conduction by segmental demyelination or axonal degeneration. Alcoholic neuropathy has been attributed to nutritional deficiencies (184) as well as a toxic action of alcohol (17). It has been noted that from 60 to 80% of afflicted alcoholics obtain complete recovery with abstinence and adequate nutrition (184).

Central Nervous System Impairment

Correlations between physical deterioration of portions of the central nervous system (CNS) and alcoholism have been demonstrated by pneumoencephalography (209), neuropathological examination (45), and by the recently developed technique of computerized tomography (150). Abnormal CNS structure has been identified in frontal, parietal, and temporal cortices; cerebellum; and the subcortical areas associated with the Wernicke-Korsakoff syndrome (294).

Electroencephalographic (EEG) assessment of the sober alcoholic has resulted in the detection of abnormal electrical activity (113), but most investigators have not found EEG assessment to be very useful in detecting brain dysfunction (16). However, sensory-evoked potentials in sober alcoholics appear to be differentiable from those of nonalcoholics (145).

Neuropsychological testing has revealed that sober alcoholics have demonstrable deficits in motor performance, perceptual capacities, conceptual shifting, visual-spatial abstracting abilities, and memory function (90,141,277), and therefore perform similarly to people with documented organic brain damage (73,265). In addition, abstracting and adaptive abilities of social drinkers who had consumed no alcohol for at least 24 hours at the time of testing were found to be negatively associated with the amount of alcohol normally consumed per drinking

occasion (208). That is, a person who averages 5 drinks per occasion is likely to have poorer scores on these tests than a person who averages 1 drink per occasion. No relationships to frequency of drinking or lifetime consumption levels were observed.

A number of investigators have estimated that CNS dysfunction is present in from 50 to 70% of sober alcoholics entering treatment, depending on the population evaluated (27,150,210).

Numerous proposals as to the etiological basis of alcoholism-associated CNS impairment have been advanced. In any one person, it is obvious that more than one of the etiological factors listed below may be involved.

- brain dysfunction may be a predisposing factor (90,278)
- malnourishment (294)
- repeated head injuries while drinking (90,141)
- other medical complications known to alter brain function (227)
- direct effect of alcohol or one of its metabolically-related products (78)

It has been reported (79) that mice fed nutritionally-balanced liquid diets containing alcohol develop permanent memory deficits and that these changes in learning capacity may be due to physical alterations in neural cells of specific brain structures, such as the hippocampus (228).

Alcohol is not considered to be a primary etiologic agent in epilepsy. However, physicians usually caution such patients concerning alcohol intake because it can be seizurogenic (156,157).

Endocrine System

Due to lack of attention by investigators and to technical difficulties in the field, relatively little systematic work has been done on the effects of alcohol on the endocrine system. The effects of alcohol on the hypothalamic-pituitary-adrenal system and the hypothalamic-pituitary-gonadal system have been studied in greater detail than most other endocrine systems. Acute alcohol administration causes increased secretion of the adrenal hormone cortisol (119,190). In chronic alcoholics, cortisol levels will also increase during withdrawal (138). Aldosterone, another hormone of the hypothalamic-pituitary-adrenal axis, may be reduced by alcohol at low doses, but increased at higher doses. Findings are conflicting, however, and further work is necessary (68). The hypothalamic-pituitary-thyroid axis does not seem to be clearly affected by alcohol use (257). Alcohol consumption inhibits the release of the posterior pituitary hormones oxytocin (81) and antidiuretic hormone (64,167). Alcohol increases insulin secretion by the pancreas, and alcoholic patients may present with diabetic-like symptoms (215).

There are known alcohol-related endocrinologic and sexual dysfunctions in male alcoholics with and without overt liver disease. Excessive alcohol intake has been associated with altered hypothalamic-pituitary-gonadal system functions resulting in reduced levels of testosterone in men (93). Furthermore, it has

been suggested that the feminizing effects of prolonged heavy drinking are due to interference with the synthesis, metabolism, and disposition of testosterone (93). These effects may be compounded by increased production of the female hormone estrogen (257). In one large study, it was noted that the second most frequent factor related to impotence in male patients was excessive alcohol intake (183). Recent case studies of women (241) and basic research in female animals (290) suggest that alcohol may induce early postmenopausal amenorrhea or even ovarian failure similar to the testicular failure and atrophy seen in alcoholic men (93).

Alcoholism

According to the National Council on Alcoholism and the American Medical Society on Alcoholism Committee on Definitions (255), "Alcoholism is a chronic, progressive, and potentially fatal disease. It is characterized by tolerance and physical dependency or pathologic organ changes, or both - all the direct or indirect consequences of the alcohol ingested".

Persons with significant alcohol-related problems have been termed problem drinkers or alcohol abusers which includes the subset of individuals suffering from alcoholism. Health consequences associated with alcoholism include a wide range of biomedical and psychosocial disorders and are discussed elsewhere in this report.

Recent evidence suggests that alcoholism may be a multifactorial genetically-influenced disorder (88). In addition to genetics, social and environmental influences play significant roles (135). At this time, much more is known about the effects of alcoholism than about its etiology.

In 1975, there were 4,897 reported deaths (289,317) with an underlying cause of alcoholism and 424,000 reported primary discharge diagnoses of alcoholism from short-term hospital stays (288,318).

Mental Disorders

Alcohol Psychoses

The term alcohol withdrawal syndrome is preferable to delirium tremens (DT's) which is a specific severe manifestation of the syndrome. DT's is an acute psychotic state with profound confusion; visual, auditory, tactile, and olfactory hallucinations; marked psychomotor activity; insomnia; elevated temperature and pulse; hyperhydrosis; and a coarse tremor often involving all parts of the body. It usually occurs after a severe and prolonged period of drinking though it may also result from simply lowering the blood alcohol level in an alcoholic person with acute injuries or infections (234,245,293). DT's is infrequently seen in individuals less than thirty years of age or in those who have not suffered serious alco-

holism for three to five years (245,293). Of alcoholics who are hospitalized, 5% develop DT's (293). Although the mortality has been as high as 20%, it has progressively decreased with better treatment in recent years. Nevertheless, death may still occur even in the absence of medical complications (279).

Acute alcoholic hallucinosis, as with delirium tremens, usually follows a prolonged drinking bout and may be seen as a variant of the withdrawal syndrome but without the usual visual hallucinations, coarse tremor, and clouded consciousness of delirium tremens in an individual with no pre-existing psychotic state. Instead, auditory hallucinations of a threatening nature, which are usually self-limited from several days to several weeks, are common in a clear sensorium which includes orientation to time and place. Chronic alcoholic hallucinosis refers to the uncommon persistence of hallucinations, usually auditory, for long periods after the patient has stopped heavy drinking (245,295).

There were 103,500 short-stay hospital discharges for all alcohol psychoses in 1975 (288,318). Of these discharges, 97,000 were for delirium tremens (DT's). There were 316 deaths in 1975 related to DT's (289,317).

Affective Disorders

An association between recurrent affective illness and alcoholism was described in 1936 (62). More recently, one study (301) of families with manic depressive disease found that there were more alcoholics in this group than expected from general population figures. Another study (253) suggested that alcoholism among women might be divided into two groups: primary alcoholism (i.e., without affective disorder) and alcoholism secondary to affective disorders (i.e., an affective disorder preceded the drinking problem). In a subsequent study of men and women, alcoholism was observed more often in first degree relatives of primary alcoholics (302). Affective disorder was seen significantly more often in the female relatives of alcoholics than what would be expected by chance alone (301,302). Nevertheless, the present data do not support a causal relationship between the two illnesses (i.e., manic depression and alcoholism), both of which might be considered primary in an individual patient (77,195). Opinion is divided as to whether involutional melancholia can be distinguished from other affective disorders (74). Involutional melancholia may be defined as late onset unipolar depression. In concordance with this definition, this kind of illness is less likely to be associated with alcoholism in the family (300).

An association between alcoholism and unipolar affective disorders such as depression has been described, both in men (186) and women (253,302). Alcoholics consistently score higher on depression on the MMPI (107) and on the Zung Depression Scale (137). Indeed, on the basis of epidemiological evidence, it has recently been suggested that there may be at least three types of alcoholism (i.e., primary alcoholism, depression-alcoholism, and sociopathy-alcoholism), of which depression-alcoholism is a unipolar affective disorder (253,302). It has been noted that the major difference between alcoholics who seek clinic psychiatric treatment and those who do not was that the former were depressed while the latter were not (304). Several studies have shown that alcohol consumption increases depression in alcoholics following an initial brief decrease (200). Depressives who have a first

degree family history of alcoholism show a different hypothalamic-pituitary-adrenal axis activity than other depressives (249).

Suicide

While suicide is defined as the act of intentionally killing oneself, the ambiguity of the circumstances which surround death by suicide and suicide attempts serve to make definition, at least for purposes of research, extremely difficult.

Alcohol consumption alters mood, judgment, and self-control and the resulting changes have been implicated in suicide (1). It has also been suggested that intoxication may stimulate suicidal thinking in already suicide prone persons and can facilitate transition from thought to action (18). Some evidence indicates that alcohol can precipitate a suicide by diminishing ego controls in certain personalities and thereby decrease the critical life-evaluating actions of the ego (282).

Physiological effects of alcohol are thought to be strongly associated with suicidal acts and attempts. Suicidal actions are likely to be more damaging in persons who are under the influence of alcohol than in persons who are sober at time of suicide attempt (15). Combinations of alcohol with other drugs often have a greater lethal potential than either drug alone. In some cases, alcohol is the drug of choice, while in others alcohol is taken to enhance another drug's effect (15,239).

Long-term problem drinking effects have been considered precipitants of suicide. Studies in this area suggest that alcoholism is several times more common in samples of suicides than in the general population. From analysis of studies of alcoholics and the association of drinking and suicide has come the suggestion that intoxication per se may be a crucial factor leading to suicide attempts in certain personality types (1). Few suicide studies have provided for adequate general population control groups to compare with samples of the population of suicides and attempters. However, one such investigation is based on samples of attempted suicides seen in a general hospital. Utilizing rigorous controls for bias and expanded time frame, the findings indicate that job, spouse, and self-reported drinking problems are uncommonly prevalent among suicide attempters (15).

Complexities of intermingled diverse social and individual elements relating to alcohol and suicide do not enhance the likelihood of discovering a single causal mechanism. Some of the theories that would explain the association of alcohol abuse and suicide are offshoots of psychological and sociological approaches to the study of suicide itself. Some of these are suicidal personality, depressive illness, desire for self-destruction through alcoholism, and social deterioration resulting from alcoholism. While studies have shown that most alcoholic persons are not suicidal and do not kill themselves, those who are high risks seem very resistant to identification and treatment (1).

Those who commit or attempt to commit suicide have a higher than expected risk of being alcoholic. According to one review, 6 to 12% of alcoholics commit suicide versus 1% of the general population, and in 11 studies of suicides, 12.7% were alcoholic (87). Another study (185) reported that 29 out of 34 patients who tried to shoot or stab themselves were alcoholic and that of those 29, 26 were intoxicated at the time of the suicide attempt. It has been estimated that between 25 and 37% of suicides involved alcohol as determined at autopsy (53). While studies such as these suggest a strong association, the specific role of alcohol to these deaths has not yet been established.

Cardiovascular

The great majority of patients in whom heavy use of alcoholic beverages leads to cardiac disease usually present with gradually occurring signs and symptoms, but occasionally the onset of the symptoms and signs of alcoholic cardiomyopathy may be sudden (226). Alcoholic cardiomyopathy generally occurs in those who have been chronic alcoholics for more than 10 years (70); however, in some, an acute illness develops which may mimic coronary artery disease (226). Patients usually present with a syndrome of heart failure, most often rightsided (57,70). The illness is often heralded by insidious or abrupt shortness of breath or cough (5). Fatigue on effort is more common than in other forms of heart failure, a finding which suggests the possibility of concomitant myopathy. Cardiomegaly is a symptom often associated with cardiomyopathy and is present in varying degrees. It is usually confirmed by chest roentgenograms, although cardiomyopathy may rarely occur without cardiomegaly (5). Blood pressure may be low, normal, or even elevated in some patients and the pulse is characteristically weak and sometimes difficult to palpate. Alcoholic cardiomyopathy is not an inevitably fatal condition and improvement frequently follows abstinence from alcohol, particularly in those patients in whom cardiac symptoms are of recent onset (57).

Morphological and physiological alterations of the myocardium in chronic alcoholics may precede the development of the clinical signs and symptoms of myocardial damage. A study of chronic alcoholics without objective evidence of heart disease, but with unexplained symptoms (fatigue, dyspnea on exertion, and nonspecific chest pain), demonstrated elevated mean left ventricular and diastolic pressure, low mean cardiac output, and depressed myocardial contractility (8).

It is important to note and distinguish acute alcoholic cardiomyopathy from the fulminant heart disease which was found among certain beer drinkers during 1965-66 (175,194). The latter disease reflected the toxic effect of cobalt sulfate, which at that time had been added to the beer for enhanced foaming (194,246).

In cardiomyopathy without associated beri-beri heart disease, cardiac output is usually decreased (5,8). High levels of circulating alcohol diminished the velocity of left ventricular contraction in dogs (87), significantly increased the workload of the heart, and reduced the coronary flow to the myo-

cardium. Such acutely intoxicated animals displayed increased susceptibility to shock (55). In spite of a decrease in cardiac output, the consumption of oxygen by the heart increased, a phenomenon which suggests a direct effect of ethanol on the myocardium (82).

Reports have been published noting that persons who consume moderate amounts of alcohol appear to have lower rates of coronary heart disease than do current nondrinkers (260,311). Alcohol consumption is known to impact on dietary habits, liver function, and circulating blood lipids, all of which may have positive or negative consequences in the pathogenesis of atherosclerosis (11,242,243). In particular, alcohol use appears to be associated with increased levels of high-density lipoprotein cholesterol, which has been negatively related to the incidence of coronary heart disease (37,48). Additional research is needed to clarify the relationship of alcohol consumption to atherosclerosis. Based on present information, advice to encourage the use of alcohol to reduce the likelihood of occurrence or recurrence of heart disease must be weighed against the attendant risks associated with increasing alcohol consumption (22,37,140,146). These risks include adverse effects on the cardiovascular system, such as hypertension, stroke, and alcoholic cardiomyopathy, as well as other health and social hazards cited elsewhere in this report (22,37,140,146).

Myopathy

Subclinical, acute, and chronic forms of alcoholic myopathy have been described (203,213). Chronic alcoholics, who do not exhibit any clinical evidence of myopathy, often have elevated activities of serum creatine phosphokinase (CPK) which is an enzyme found in muscle (247). Oh (203) has estimated that subclinical myopathy, indicated by elevated serum CPK, is present in over one third of chronic alcoholics. Asymptomatic myopathy is often characterized by a history of muscle cramps, weakness, and occasionally intervals of dark urine.

Acute alcoholic myopathy may be indicated only by the sudden onset of weakness (104). By contrast, in severe cases, there is a sudden onset of pain in skeletal muscles, or there may be a rapid progression of a previous chronic myopathy (47). Severe cases may be distinguished by myoglobinuria, and can end fatally (104). In acute alcoholic myopathy, the muscles are generally very tender and weakness is often related to one limb or group of muscles, although in some cases it may be more diffuse. This disorder is generally reversible upon discontinuation of alcohol consumption (270).

In some chronic alcoholics, the development of alcoholic myopathy is reflected in an insidious onset of muscle weakness and atrophy (65,212). Electromyographic evidence of proximal myopathy is common, and such patients usually disclose a myopathy upon biopsy. In these cases, the involvement is usually symmetrical, and the most conspicuously affected muscles are commonly those of the proximal lower extremities.

The course of chronic myopathy may be complicated by acute myopathy, especially after a drinking spree (212). In most of these cases, discontinuation of alcohol abuse leads to improvement in muscle physiology (212).

Although a nutritional basis for alcoholic myopathy has been suggested, it has been clearly demonstrated that the serum CPK activity may be elevated and electron microscopic changes occur in skeletal muscle of healthy volunteers given a nutritionally adequate diet and alcohol for 28 days in quantities approximating those consumed by alcoholics (270). These findings suggest a direct and deleterious effect of alcohol.

Phosphate deficiency in chronic alcoholics has been suggested as a cause of acute alcoholic myopathy (144). Rhabdomyolysis (dissolution of muscle tissue) occurs in some alcoholics and is often associated with hyperkalemia (excessive potassium in the blood) and renal failure (67,105). Hyperkalemia, in turn, has been implicated in changes in heart physiology which sometimes lead to death.

Cancer

The observation that many patients with cancer of the mouth, pharynx, larynx, esophagus, and liver are found to be alcohol dependent or have alcohol-related cirrhosis has stimulated research into the possible role alcohol might play in carcinogenesis. Heavy drinking increases the risk of developing cancer of the tongue, mouth, oropharynx, hypopharynx, esophagus, larynx, and liver. In the U. S., these sites represent 6.1 to 9.1 percent of all cancers in the white population and 11.3 to 12.5 percent in the black population (283).

In 1964, the World Health Organization (306) surveyed the research on alcohol use and cancer to that time and concluded that: 1) the association between excessive drinking of alcoholic beverages and cancer of mouth, larynx, and esophagus had been demonstrated in several epidemiological studies, 2) animal studies had so far failed to support this finding, and 3) alcoholism is associated with other factors that may increase the incidence of cancer, including dietary deficiencies. Furthermore, the frequent coexistence of alcohol and tobacco use has made it difficult to identify the independent influence of each substance in relation to cancer.

The means by which alcohol might exert a carcinogenic effect are unknown. Several mechanisms were recently reviewed at a joint NCI/NIAAA conference (96) and are currently being studied. Among the possibilities are alcohol-induced immunological suppression; effects of prolonged and repeated contact of body tissues with alcohol, especially in strong solutions; alcohol as a cocarcinogen with tobacco, or as a trigger mechanism for a hypothetical viral cause; indirect consequences of heavy alcohol use, such as malnutrition, anemia, and poor hygiene; and the possible presence of carcinogenic substances in some alcoholic beverages.

Cancer of the Buccal Cavity, Pharynx, and Larynx

Cancers of the mouth, pharynx, and larynx appear to be related to heavy drinking in the U. S. and other parts of the world where these cancers occur with high frequency (211,250,276). Although the use of tobacco in one form or another is the most important worldwide link to cancer of the mouth (106), risk is further increased among people who also drink heavily (307). The roles of smoking and drinking in cancers of the upper aerodigestive tract have been difficult to separate due to the association of heavy drinking and smoking in the same individuals (136). For example, one study showed that 93 percent of men and 91 percent of women in a group of alcoholic outpatients were smokers, proportions far higher than those observed for the general population (61).

A number of investigations have been concerned with determining the relationships between drinking, smoking, and oropharyngeal cancer. In a case control study of 543 men and 116 women, Wynder et al. (309) found that consumption of alcohol was an important factor in addition to that of cigarette smoking. Keller (131) reviewed 408 cases of mouth and pharyngeal cancer and found that smoking, drinking, and cirrhosis of the liver were all independently associated. Rothman and Keller (236) studied the smoking and drinking experiences of 483 persons with cancer of the mouth and pharynx and 447 controls. Relative risk was accelerated with increased exposure to each factor at every level of exposure to the other, which demonstrates either the existence of a strong independent or interactive effect for smoking and drinking. These authors calculated that 76 percent of the disease in males might be eliminated if exposure to both alcohol and tobacco were avoided. Wynder and his colleagues (309) found that patients with oral and laryngeal cancer were considerably heavier drinkers than control patients. By separating individual risk factors in oral cancer, they concluded that "heavy drinkers" had roughly a 10 times greater risk of developing cancer of the mouth than "minimal" drinkers. When amount of alcohol consumed increased, the relative risk of cancer of the mouth, extrinsic larynx, and esophagus was also increased, much more so with whiskey than beer and wine (309).

Malnutrition and anemia are also associated with increased risk of oral, hypopharyngeal, and esophageal cancer (309), and it is possible that the increased risk of oral cancer in alcoholics may also be related to the nutritional deficiencies associated with heavy alcohol intake.

Cancer of the Esophagus

While there were only 2.7 cases of esophageal cancer per 100,000 population in the U. S. in 1957, 69 percent of the patients with cancer of this site also had a history of heavy alcohol use (172). Investigators have shown a relationship between heavy drinking, especially of whiskey or other spirits, and esophageal cancer after corrections for age and tobacco use were made. Smoking has been reported to be less important than alcohol in esophageal cancer. Indeed, smoking in the absence of heavy drinking appeared to have little or no effect on its development (308).

In certain parts of France, Tuyns (284) has shown that mortality from esophageal cancer is more highly correlated with mortality from alcoholism than with mortality from cirrhosis. Martinez (181,182) reported on an extensive retrospective study in Puerto Rico of 400 patients with cancer of the esophagus, mouth, and pharynx and 1,200 controls matched for age and sex. The relative risks rose with increased alcohol consumption, becoming 2 to 6 times higher among heavy drinkers than among nondrinkers. The risk was 2.5 to 5 times higher for heavy smokers than for nonsmokers. Alcohol and tobacco were found to be the outstanding factors associated with these cancers. Apparently they operated independently, with tobacco second in importance to alcohol in determining the different degree of risk between patients and controls. A similar situation was observed in Brittany and Normandy, where a correlational study suggested the possible role of regionally produced cider and distilled derivatives (284).

Other environmental factors may also play a role in the pathogenesis of esophageal cancer. For example, certain occupations have heavier risk (169). Iron and vitamin deficiencies, as well as the drinking of hot beverages have been reported to be associated with esophageal cancer (308).

Gordon et al. (94) reported an increase of esophageal cancer among nonwhite males and females. Increased heavy smoking and drinking, together with changes in living standards, diet, and urbanization are factors requiring further investigations. U. S. rates for esophageal cancer in whites have been reported to be stable (94) or decreasing (251). In Europe, shifts of mortality from esophageal cancer have been attributed largely to changes in drinking habits among the population involved (285).

Morbidity estimates of association between alcohol and carcinoma of the esophagus range from 28.8 to 80% (136,162).

Cancer of the Large Intestine and Rectum

Breslow and Endstrom (26) correlated the per capita consumption of cigarettes, spirits, wine, and beer in 41 states (as estimated from tax receipts) with the annual age-adjusted rates of death from cancers of 20 sites between 1950 and 1967. The strongest single association was between death from rectal cancer and beer consumption. Similar findings of higher incidence of rectal and colon cancer in beer drinkers have been reported (252,310). Drasar and Irving (60) have hypothesized that dietary constituents, including beer, may influence bacteria and steroids in the gut, and thus, the concentration of possible carcinogens.

Although the above investigators have postulated a relationship between cancer of the large bowel and heavy beer drinking, the results of other studies have not consistently supported this hypothesis (54,120).

A causal relationship has not been established, and further research into the apparent association between beer drinking and rectal, colon, and large-bowel cancer is needed.

Primary Cancer of the Liver

Worldwide, 69 to 90% of all liver-cell cancer arises in cirrhotic organs, and in Europe and North America, the typical person who develops primary cancer of the liver (hepatoma) is an alcoholic with cirrhosis (106). Primary liver cancer seems to occur 2 to 8 years after the onset of cirrhosis (222). However, hepatoma may also occur in alcoholics even in the absence of cirrhosis, which may indicate hepatic damage below the threshold of clinically or histologically identifiable alcoholic cirrhosis.

Studies generally have shown that there has been an increase in the number of cases of cirrhosis associated with hepatoma (176,222). A common explanation is that the medical management of cirrhotic patients has improved over the years to the point where the lives of such patients have been prolonged, increasing the probability of malignant degeneration of their damaged hepatic cells. Despite an increase in primary liver cancer reported in autopsy studies, data published by cancer registries in various countries do not seem to reflect this trend. These apparently contradictory findings may simply be due to a greater number of autopsies performed in better equipped hospitals over the years; if the autopsy rate is high in a population for which a cancer registry exists, the incidence of primary liver cancer may appear surprisingly high (286).

The mechanisms by which alcohol increases the risk of primary liver cancer are probably similar to those of other liver-damaging agents, and the probability that a hepatoma will develop is increased once this damage occurs. More specifically, cancer develops characteristically in livers with large nodular hyperplasia, a stage of cellular regeneration activity, regardless of the cause (136). This agrees with the observation that patients with well-established cirrhosis who stop drinking may still develop tumors. Further, a higher incidence of hepatoma was observed in mild and healed alcoholic cirrhosis than during the severe acute state (244). Viral hepatitis resulting in cirrhosis and subsequent neoplastic changes has been implicated as another etiologically important factor. In the U. S., alcoholic rather than post-hepatitis cirrhosis is the more important factor in liver-cell cancer, while in other parts of the world this does not appear to be true.

Mortality estimates of alcoholic association with liver cancer range from 28 to 86% (53,136).

Cancer of the Pancreas

In the last few years, cancer of the pancreas has become the third leading cause of cancer death among men 34 to 54 years old in the U. S., particularly among black men. Since blacks in this age range work in certain industrial occupations in disproportionate numbers, and drink and smoke more than white men of the same age, these factors have been suggested as potentially increasing the risk for this cancer (147). Some investigators believe that the pancreatitis often associated with heavy alcohol use may be the mechanism that links alcohol to cancer of the pancreas (30).

On the other hand, in their review of the distribution pattern of cancer of the pancreas, Levin and Connelly (158) note that the age-specific sex ratios for mortality from cancer of the pancreas differ substantially from cancer at sites with a strong association to alcohol consumption, namely cancer of the esophagus and the liver. These ratios of pancreatic cancer death are more similar to those for diabetes mellitus, a disease which has also been proposed as etiologically important in the development of pancreatic cancer (158). Thus, the evidence that alcohol consumption is a significant risk factor for pancreatic cancer remains to be established.

Infectious Diseases

Pneumonia is a frequent cause of illness and death for alcohol abusers. In one U. S. medical center, 50% of all patients admitted with pneumonia were alcoholics (173). The neglect of nutrition, impairment of lung clearance, phagocytosis, and decreased immune response mechanisms make alcohol abusers prone to respiratory infection.

As with other respiratory infections, tuberculosis appears more frequently among alcoholics than among the general population. In addition, since the Skid Row type of chronic alcoholic often works as a food handler or dishwasher, he or she may be a prime source of the spread of tuberculosis (173). In recent years there has been a significant trend toward an increased percentage of alcoholics among tuberculars (63). This may be an artifact related to an overall decrease in tuberculosis, allowing a subgroup of chronic alcoholic patients to increasingly dominate the shrinking population of all tuberculars. Alcohol's association with tuberculosis deaths ranges from 20 to 70%, according to various studies (63,173).

Alcohol Intoxication

Alcohol intoxication produces a wide variety of alterations in coordination, sensory-motor processes, cognition, and emotions. Some of these contribute to traffic accidents, violence, suicide, and crime. Other acute effects of alcohol are pleasurable and undoubtedly contribute to the popularity of alcoholic beverages.

Psychological Impairments

Motor impairments, such as staggering walk, unsteady balance, and slurred speech are probably the most obvious behavioral changes in intoxicated people (214,297). A recent comparative study reported that body sway was most sensi-

tive to alcohol's effects, showing significant impairment at fairly low blood alcohol levels of 0.04% (76).

Relatively small amounts of alcohol can significantly prolong glare recovery times producing a period of relative blindness that can be particularly hazardous for intoxicated automobile drivers (4). In addition, alcohol impairs the ability to adapt to variations in light (160) and performance on tracking tasks which involve eye-hand coordination (196,297).

It is well established that rapidly achieved high levels of blood alcohol can produce blackouts or total amnesia for events experienced during a drinking episode (89,91). More common is the less severe form of memory loss that occurs in both alcoholics and social drinkers after moderate consumption of alcoholic beverages (240). Most drinkers are not aware of these partial memory losses that occur when they drink alcohol, and the mechanisms underlying these deficits are not yet fully understood (21).

Although alcohol has relatively little effect on the ability to attend to information from a single source (concentrated attention), it has a detrimental effect on the capacity to attend to information from more than one source (divided attention) (197,198). This is thought to reflect a slowing of central processes rather than an effect on sensory systems and may be due to alcohol-induced impairments in the brain's capacity to switch from one source of information to another (196). It has also been reported that moderate alcohol intoxication impairs the selection and organization of appropriate responses (280).

The effects of alcohol on emotional states in humans depend on characteristics of the drinker, the drinking environment, and the amount of alcohol consumed. The ingestion of moderate amounts of alcohol by social drinkers has been related to increased positive feeling states (128,130), especially in social situations (218). Alcohol consumption also has been shown to increase social interactions in social drinkers (267) as well as in alcoholics (95). A positive effect of small amounts of alcohol on social interaction has been reported in institutionalized geriatric patients (193).

In contrast to these positive findings associated with moderate consumption, it has been concluded that there is limited and inconsistent support for the commonly-held notion that alcohol reduces stress or tension (33). Furthermore, drinking has been associated with increased hostility or aggression in certain environmental contexts (e.g., social situations) at blood alcohol concentrations of 0.08% and higher (35). Lastly, it is important to note that the aging brain may be more sensitive to alcohol-related neuropsychological impairments than the younger brain (124).

Alcohol Poisoning

Blood alcohol levels in the range of 0.25-0.40 percent begin to affect the diencephalon, manifested by apathy, inertia, cessation of automatic movements, and eventually stupor or coma. Higher levels of alcohol block the centers in the medulla which control breathing. Depression of respiration, peripheral collapse, subnormal temperature, and death rapidly ensue. Official death certi-

ficate data in 1975 listed 391 deaths per year directly attributable to alcohol poisoning as the underlying cause of death (289,317).

Accidents

Alcohol has also been seriously implicated in accidental death and injury resulting from home, industrial, recreational, and motor vehicle accidents (1). Self-defined regular drinkers are involved in more accidental injuries than occasional or nondrinkers (275). Heavier drinkers appear to have more accidents than other people (1). Further, those who are alcohol dependent have a considerably higher rate of accidental death than the general population. Studies have reported that the risk of accidental death from falls is 16.3 times higher for alcoholics than for the general population. Similarly, the relative risk of accidental deaths for alcoholics is 2.0 to 5.7 for other non-traffic accidents, 4.5 to 5.0 for traffic accidents, and 2.0 to 4.0 for suicides (51,211).

The following discussion of the role of alcohol consumption in accidents includes some estimates which vary widely. These estimates reflect differences in the definitions of alcohol use and abuse, differing characteristics of the groups studied, and differing study methods.

Motor Vehicle

Traffic accidents are the greatest cause of violent death in the U. S., resulting in more fatal injuries than any other accident type and causing almost as many fatalities as homicide and suicide combined (1). Approximately one third of the deaths resulting from traffic accidents are related to alcohol consumption (314).

More studies exist on fatal than nonfatal crashes. Although research findings vary substantially on the extent of alcohol involvement in various types of crashes, general trends seem to support the following statements concerning the relationship of alcohol and traffic crashes (1).

1) From 6 to 25 percent of drivers in non-fatal crashes had BAC's (blood alcohol concentration) of 0.10 percent or higher.

2) From 35 to 59 percent of drivers in fatal crashes had BAC's of 0.10 percent or higher.

3) From 17 to 29 percent of passengers in fatal accidents showed BAC levels in the legally impaired range.

4) Alcohol could be involved in 25 to 83 percent of pedestrian fatalities.

5) From 41 to 72 percent of drivers in single-vehicle fatalities and 18 to 51 percent of drivers in multivehicle fatalities had BAC's of 0.10 percent or higher.

6) Of the drivers in multivehicle fatal crashes with BAC's in the high range, 31 to 44 percent were judged by researchers to be responsible for the crashes, compared to 7 to 12 percent judged not responsible.

Data from a number of case-controlled studies reveal that even after controlling for exposure to accidents, the relative probability of crash involvement and causation increases dramatically as the BAC rises (24). Although there is substantial variation among studies in the relative risks associated with particular BAC's, the general pattern shows that the risk of fatal and serious injury crashes sharply increases above blood alcohol levels of 0.08 percent (24). Moreover, comparative data show that the relative probability of causing a crash rises more sharply than the relative probability of merely being involved in a crash at BAC's of 0.05 percent and higher (69). At a BAC of 0.05 the relative risk for crash involvement and causation is 1.5 times that at the 0.02 level. When the BAC is 0.10, the relative risk doubles for crash involvement and quadruples for causing a crash (relative to the risk at a BAC of 0.02); with a BAC of 0.16, the likelihood of being involved in a crash is four times greater (1).

Although there is considerable variation as to the relative risk associated with specific BAC's and specific demographic characteristics, there seems to be much greater risk for certain demographic groups than for others. For example, the relative probability of accident involvement associated with BAC is markedly different for various age groups (313). At all BAC's, male drivers in the age ranges of 18 to 24 and of 65 and older have a higher relative risk of being involved in a crash than all other male drivers. As BAC increases, this pattern is accentuated, with the relative risk of accident involvement increasing more sharply for very young and very old drivers than for middle-aged drivers (1). Studies also have shown that a larger proportion of men than women had been drinking at the time of the crash (24), and that the majority of alcohol-related accidents occur at night (174).

A well-publicized concept is that a large proportion of people involved in traffic accidents have histories of alcohol-related problems and can be labeled problem drinkers or alcoholics (256). Yet reports are inconsistent in indicating the proportion of crashes that involve alcoholics and problem drinkers.

Experimental studies focusing on the acute effects of alcohol have demonstrated that alcohol causes degeneration of driving skill, including reaction time, coordination (196,297), visual awareness (4,160), attention (196,197,198), as well as impairment of judgment (297). However, the full extent to which alcohol use results in traffic accidents due to these impairments is unknown. Some researchers believe that physiologic impairment of sensory-motor functions caused by acute alcohol intoxication is the most important factor responsible for alcohol-related traffic accidents (296). Others have demonstrated that decreased tolerance to tension, recent stress, hostility, depression, impulsivity, and suicidal tendencies are present in a significant number of alcoholics

involved in accidents (34,258,261). Sufficient data do not yet exist to discriminate effectively between these factors (1). Alcohol use has been implicated in 7 to 83% of traffic fatalities (1).

Industrial Accidents

Interest in the relationship of alcohol to industrial accidents was stimulated after Jellinek's research on the problem of alcoholism in the 1940's (118). He claimed that there were then 1,370,000 alcoholics employed as industrial workers in the U. S. who had twice the fatal accident rate of the nonalcoholic working population. As a result of this study, alcoholism was considered a major problem in industrial safety, and other studies were initiated to identify the problem drinker, to estimate the production losses caused by alcoholism, and to determine the number of accidents directly related to alcohol use in the U. S. Studies soon expanded beyond the narrow definition of industrial accidents to include other production losses due to alcoholism such as absenteeism and off-the-job accidents. However, none of the American studies focused on BAC's of industrial accident victims.

Alcohol can inhibit coordination and judgment, lengthen reaction time, and decrease motor performance and sensory skill in simulated industrial work. Wolkenberg's experiments on the effect of alcohol intoxication on normal persons demonstrated changes in performance up to 18 hours after the ingestion of alcohol (303).

Problem drinkers have a greater likelihood of being involved in industrial accidents than the general population. The relative risk of industrial accidents for alcoholics compared to nonalcoholics is in the range of 2 to 3 (202,291). The range of estimates of alcohol involvement varies from 9 to 40% for fatalities and 7 to 47% for injuries (1).

Fire and Burns

Alcohol use and abuse have been implicated in the cause of fires and in the failure to detect and escape from them. Studies have reported evidence of alcohol use in 9 to 87% of fire fatalities and 15 to 62% of burn injuries (1).

A history of alcoholism seems to be related to fire involvement. Studies have found that 23% of nonfatal burn victims and 26 to 53% of fatal fire victims were alcoholics (46,97). A Canadian study found that alcoholics have a 9.7 times greater risk of dying in a fire than do nonalcoholics (250). Followup studies from several countries indicate that approximately 1% of all alcoholics die in fires (1).

Cigarette smoking is a major contributing cause of fires and a clear association exists between drinking and smoking in the general population. Positive BAC's occur in nearly three times as many cigarette-caused fire deaths as in fires not caused by cigarettes (111).

Falls

Falls are the most common cause of accidental death in the U. S. after motor vehicle accidents (201). From 10 to 70% of deaths from falls involved alcohol, and between 0.3 to 3.5% of alcoholics die from falls (1). Alcoholics were found to have 5.6 to 13.3 times the risk of dying from a fall than the general population (25,201,250). Between 13 to 63% of all injuries resulting from falls involved alcohol use (1).

Aviation, Boating, and Drowning

A substantial proportion (14 to 44%) of general aviation crashes may involve alcohol consumption at or near the time of the accident (1), more so for general aviation pilots than military pilots (52,266,312).

Boating accidents accounted for 1,570 fatalities in 1975, of which at least 14% or 220 deaths were estimated to involve alcohol misuse (1).

Drowning, a major category of accidental death in the U. S., was the cause of 7,130 deaths in 1975 (289,317); 85% were males, and 60% were under the age of 25 (201). Positive BAC's have been found in 4 to 83% of drowning victims (1).

Alcohol-related drownings are concentrated among middle-aged persons (83,219). Alcohol use also appears to be more common in swimming deaths than in other types of drowning (58). Further, among swimmers it appears that victims who had been drinking included more good or average swimmers than victims who had not been drinking (221).

Researchers long have recognized alcohol's potential role in drownings. Swimmers may take more risks, such as swimming farther from shore than they normally would; also, the "pseudowarmth" effect of alcohol may encourage remaining in cold water too long, causing overexposure and subsequent drowning (221). In these situations, alcohol may depress the swallowing and breathing reflexes.

Pharmacology and Drug Interactions

Pharmacology

Alcohol for consumption is ethyl alcohol, or ethanol, and is classified as a reversible general central nervous system depressant (229). Ethanol is found in various beverages and ranges in concentration from approximately 4% by volume in beer, to 12% in table wines, and from 40% to 50% in distilled spirits. Alcoholic beverages also contain a variety of other constituents

collectively categorized as congeners, which although generally present in low concentrations, can be toxic (134).

Ethanol is absorbed from the alimentary tract with most absorption occurring in the small intestine. Rate of absorption varies and is a function of type of beverage, concentration, pH, food ingestion, as well as other physiological processes. Ethanol is distributed fairly uniformly throughout body fluids and tissues (126). Consequently, variations in body fat distribution, body mass, and in body water can result in different pharmacokinetic relationships, for example in men versus women and in fat versus thin people.

With low doses, ethanol possesses transient stimulatory properties, especially when blood alcohol levels are rising, which subsequently change to sedative and hypnotic properties. As the dose is increased, ethanol produces the full spectrum of central nervous system depression, ranging from sedation to general anesthesia to death (229).

Although small amounts of ingested alcohol are lost in the breath, sweat, and urine, most ethanol is eliminated by metabolic oxidation. This process takes place primarily in the liver where three reaction mechanisms are capable of oxidizing ethanol to acetaldehyde: alcohol dehydrogenase, catalase, and microsomal ethanol oxidizing system. Alcohol dehydrogenase is clearly the most important enzyme in vivo (103), whereas catalase normally accounts for only a small percentage of ethanol metabolism (165,205). The microsomal ethanol oxidizing system appears to be inducible (102,122), and it has been suggested that chronic alcohol ingestion might result in an increased rate of metabolism of alcohol (281) as well as certain other drugs. The microsomal ethanol oxidizing system has not yet been studied in humans. Changes in rate of metabolism vary with time of day (123,299), previous drinking history, nutritional status (23), and genetic factors (292).

An acquired change or tolerance results from repeated exposures to ethanol such that an increased amount must be consumed to produce a characteristic response. Although tolerance is often thought to develop only after chronic exposure to ethanol, some investigators have reported that it can be demonstrated after 2 to 3 weeks (3,116,189,298). It has also been suggested that learning processes may be involved in the acquisition of tolerance (39). Other investigators have noted that the degree of impairment in various physiological and behavioral measures is greater at a given ethanol concentration in the rising phase of the blood alcohol curve than at the same concentration in the descending phase (7,36,86,273). This phenomenon has been called acute tolerance (127).

Following the development of tolerance and after continued heavy ethanol consumption, the abrupt cessation of drinking may result in a variety of pathophysiological disturbances. These disturbances are called the withdrawal or abstinence syndrome and indicate that the person was physically dependent upon the presence of ethanol to function at a seemingly normal level. These pathophysiological disturbances can include such clinical symptoms as hallucinatory psychoses, shakes, seizures, extreme tremulousness, diaphoresis, ataxia, and in general, signs of intense central nervous system hyperexcitability (293).

The relationship between tolerance and physical dependence is complex as indicated by clinical and experimental observations. Physical dependence does not invariably accompany tolerance even though people physically dependent upon ethanol are also tolerant. Characteristics associated with physical dependency begin to subside sooner than those associated with tolerance. Investigators have indicated that tolerance and physical dependence may be mediated through different mechanisms (230).

Drug Interactions

It has been well documented that ethanol can affect the pharmacologic and therapeutic actions of a number of other drugs, and similarly, can have its own actions altered (134). These interactions can be classified as antagonistic, additive, or supra-additive (134). Direct interactions involve the basic pharmacologic effects of alcohol and the other drug at the same site of action. Indirect interactions occur when one agent affects the absorption, distribution, and elimination or metabolism of the other.

Adverse effects from ethanol-drug combinations are sometimes deliberate, as in many suicides and suicide attempts (110), and in attempts to produce mood alteration (232). Usually, however, the possibility of ethanol-drug interactions is overlooked, and adverse reactions occur accidentally. Although most ethanol-drug interactions occur after heavy and continuous drinking, some can occur even after a single drink (e.g., disulfiram) (10).

Ethanol can interact with legitimate drugs commonly prescribed by physicians, with minor tranquilizers being the most frequent (71). Additive and supra-additive reactions have been reported between ethanol and barbiturates, minor and major tranquilizers, anesthetics, ethanol analogs, and morphine and other opiate derivatives (134,254). Antagonist interactions have been noted for ethanol and stimulants (134,254). Ethanol also interacts with certain types of antidepressant drugs, anticonvulsants, warfarin-type anticoagulants, antibiotics, antihypertensives, and drugs producing alcohol intolerance such as disulfiram (134,254).

Ethanol can also interact with self-prescribed, over-the-counter drugs. For example, antihistamines have a prominent side effect of sedation, and have been reported to intensify the impairing effects of alcohol on performance skills (262). Aspirin can cause massive gastric hemorrhage in alcoholics who have low prothrombin levels and alcoholic gastritis (134).

A sizable proportion of people using illicit drugs such as hallucinogens, cocaine, opiates, inhalants, and marihuana, combine alcohol with these drugs (2); this practice can have hazardous consequences. For example, the combined use of opiates and ethanol potentiates the effects of both drugs and can increase the probability of death (134). Furthermore, alcohol combined with marihuana results in worse performance on tests of perceptual, cognitive, and motor functions than with either substance alone (41,177,179). Among those adults who have ever used marihuana, more than one fourth report combining it with alcohol, as do roughly one fifth of all cocaine users (29). One fifth of methadone users also became secondarily addicted to alcohol (134).

Thus, combining alcohol with other "drugs of abuse" appears to present a special problem.

Alcohol in combination with other drugs has been reported to be the second most frequent cause of drug-related medical crises in the U. S. (115). In addition, the harmful consequences of combined ethanol-drug use are not always strictly medical, but also include behavioral effects which may precipitate hazardous consequences such as accidents (31,262).

METHODS TO INFORM THE GENERAL PUBLIC OF THESE HAZARDS

PART III

PART III - INFORMING THE PUBLIC ABOUT HEALTH HAZARDS

"The actions which should be taken by the Federal Government under the Federal Alcohol Administration Act and the Federal Food, Drug, and Cosmetic Act with respect to informing the general public of such health hazards..."

Introduction

In assessing actions the Federal government should take to inform the general public of the alcohol-related health hazards discussed in Parts I and II of this report, the Departments, through a variety of methods, solicited expert advice on two basic questions:

- Many alcohol-related problems pose potential health hazards. Which problems most urgently require government involvement in informing the public?

- Many techniques are available for communicating messages to various audiences. Which techniques would be most efficient and effective in communicating information about alcohol-related problems?

As a way of identifying future new initiatives, the Departments reviewed many of the extensive Federal and private efforts already underway to inform the public about alcohol-related health hazards. These national public education programs (summarized in Appendix C) involve several Federal Departments, including Health and Human Services, Treasury, Transportation, and Education. In addition we looked at the efforts of States and local governments, the beverage alcohol industry, the scientific, medical and social welfare communities, religious bodies, educational systems at all levels, industry, labor, and civic and voluntary organizations, including those directly involved in the prevention and treatment of alcohol abuse and alcoholism.

These public information and education efforts were taken into account as we evaluated the scope of possible action the Federal government might take under the Federal Alcohol Administration Act (FAAA) and the Federal Food, Drug, and Cosmetic Act (FFDCA) with respect to informing the general public of alcohol-associated health hazards. An analysis of the relevant statutes is included as Appendix D.

Part III is organized into three sections. The first section summarizes five major health hazards selected for special attention. The second section addresses communication techniques that might be used to inform consumers of these hazards, with particular attention to what is known about the effectiveness of warning statements, such as those used on cigarette packages and products containing saccharin. The third section presents recommendations for action.

FIVE MAJOR HEALTH HAZARDS

Parts I and II of this Report discuss a wide variety of harmful effects that alcohol consumption can have on the human body. The Report does not attempt to make recommendations dealing with all of the potential problems cited, since both the public's ability to receive messages and the government's ability to deliver are limited. Instead, the Report focuses only on those problems which in our judgment, after reviewing the views expressed by our consultants and respondents to the Federal Register Notice, are the most severe or prevalent, as well as susceptible to improvement by public information efforts.

Five major problem areas were selected for special attention:

- Fetal Alcohol Syndrome (FAS) and other alcohol-related birth defects. Although scientific evidence concerning prevalence is not yet fully determined, the potential for damage to the unborn is significant. Because scientific evidence linking alcohol and birth defects is relatively recent and continuing to unfold, it is particularly important to generate a high level of public awareness of these risks in order to prevent them.

- Alcoholism. This is a prevalent disease and a major public health problem resulting in lost productivity, destruction of health and family and much human misery. Numerous myths and misconceptions continue to surround alcoholism and alcohol abuse.

- Major medical consequences. This Report summarizes many physical and psychological consequences of alcohol consumption. Many individuals are apparently unaware that certain levels of alcohol consumption have been linked to some forms of cancer and heart problems. Research is continuing and results need to be communicated.

- Accidental death and injuries. Consumption of alcoholic beverages is a major factor in traffic fatalities and an important cause of industrial accidents.

- Alcohol-drug interactions. The proliferation in use of legal and illegal drugs has increased the severity of this problem. Many drug users are apparently unaware of the potentially dangerous interactions between specific drugs and alcohol.

COMMUNICATING HEALTH MESSAGES ABOUT ALCOHOL

The communication of effective alcohol-related health messages is particularly challenging and difficult. Few products in our society can match alcohol in its ability to evoke strong sentiments--both positive and negative. Most people already have firm opinions concerning the appropriate role of alcoholic beverages in their personal lives, and such perceptions, whether based on accurate information or not, are highly resistant to change.

These perceptions may be acquired through personal experience with alcoholic beverages, or the experiences and influence of associates, friends and family members. Perceptions may also be acquired vicariously through the depiction of alcohol use in publications and films, radio, and television dramatizations. Unfortunately some of the perceptions are incorrect. A Gallup Poll (July, 1978) found that about one person in 12 believed there are no risks involved with regular use of alcohol. Other perceptions are incomplete. Many people do not know how alcohol is metabolized in the body and have incomplete knowledge about the effect that food or time can have on this process; they also assume, incorrectly, that coffee can have a mitigating effect. People are insufficiently aware that consumption of large amounts of alcohol in a short period of time, such as may occur in a drinking contest, can cause death. They are also unaware that drinking can cause or contribute to the various health hazards discussed in the report.

A very important source of perceptions is alcoholic beverage advertising, particularly for young people. For example, the Surgeon General's Report, "Healthy People," identifies the "favorable image afforded alcohol use in television advertising and programming" as one factor in the inability of some recent alcohol education efforts to change children's behavior (11).

The alcoholic beverage industry commits hundreds of millions of dollars annually to an extensive array of product advertising, print and broadcast. Professor M.D. Lambert of the University of Washington in Seattle analyzed 504 copies of 42 popular magazines issued in 1978 finding 3,131 alcoholic beverage advertisements. The greatest number of advertisements (1,060) appeared in Playboy, Psychology Today, Cosmopolitan, and Penthouse (7). In 1977, the latest year for which we have figures, network television carried about 5,000 beer and wine ads, mostly during evening prime time shows and weekend sports programs. These advertisements, particularly the beer advertisements, associate the use of the product with attractive individuals, enjoyable activities, and pleasant surroundings, without communicating any of the potential negative consequences.

Keeping in mind the pervasiveness of positive images concerning alcohol use in American society, the Departments sought during the consultation process to identify communication techniques which could be effective in carrying appropriate health-related messages about alcohol use to current or potential users. The purposes of any such communication, be it a mass media campaign, product labeling, or educational effort, involve attempts to inform, raise awareness levels or reinforce old knowledge, and/or change potentially harmful behavior.

We first evaluated previous Federal efforts designed to provide the public with health information about other potentially hazardous products. Because the Congress and others have shown particular interest in warning labels as a means of informing the public, we included in this review an examination of evidence regarding the effectiveness of the health warning on cigarette packages and products containing saccharin, an evaluation of health warnings generally, and an analysis of advantages and disadvantages of an alcohol warning label. The Departments also considered a wide range of possible communication techniques that could be used to carry health-related messages about alcohol.

Warning Statements as a Method of Informing the Public

The Departments considered many factors before arriving at a recommendation concerning health warnings on alcoholic beverage containers. These included:

- o General receptiveness of the public to government-initiated health warnings.
- o The type of health warning which is likely to be effective in communicating information and influencing behavior.
- o The methods through which warnings can be effectively and credibly presented.
- o The public's right to know, and the nature of the Federal government's obligation to inform the public about scientifically established health hazards.

Public Receptiveness

Several communications experts cautioned that the public generally is feeling "over warned" by the government. Dr. Amitai Etzioni, for example, wrote "that growing segments of the public ignore more and more of such (government) warnings because they feel they cannot heed the recent avalanche of warnings" (4). People seem to particularly resent being "warned" about negative consequences likely to result from use of products which they enjoy consuming, which may appear to relieve stress, and about which they feel personally knowledgeable and comfortable.

The reaction is heightened when there are few or no comparable substitute products, as in the case with alcohol, or saccharin and cigarettes. In these instances, a consumer is forced to give up a habit or the use of a type of product entirely rather than the less difficult act of switching to a comparable substitute. For example, many consumers switched readily to non-aerosol cans when warned of the potential danger of fluorocarbons to the environment.

The general sense of being over-warned may not extend, however, to product use statements which appear on a wide range of items, including power tools, lawnmowers, household cleaners and prescription drugs, to name but a

few. These messages often include specific warnings on possible negative consequences of product misuse. While these messages are often required by regulation or statute, they do not appear, however, to be government warnings. Therefore public acceptance of warnings may also depend on who the public perceives to be the source of the warning.

A few manufacturers also use product disclaimers in advertisements. Preliminary data from one study of alcoholic beverage advertising indicate that public perception of a product was enhanced by the inclusion of a statement encouraging moderation. In that experiment, participants perceived magazine ads containing a statement such as "Enjoy Our Quality Product in Moderation" to be significantly more believeable, useful, good and effective than identical ads without the disclaimer. The study also found that the disclaimer enhanced rather than detracted from the product's image. The researchers surmised that "Perhaps the disclaimer serves to enhance the image of the company because the audience perceived the advertiser as more socially responsible and concerned about the health of consumers" (2).

Types of Warnings

The communications experts consulted also indicated that the way in which warning messages are presented significantly affects the success of a particular persuasion effort. Messages tending to instill a high level of fear, for example, are generally not as effective as more positive approaches which suggest constructive alternative action (4). A high level of fear may cause the audience to feel overly threatened and, as a result, to screen out the message. The impact of a fear-inducing message is also strongly influenced by the perceived accuracy of the information being transmitted. If the message content conflicts seriously with the personal experiences of the audience to whom it is directed, it is likely that the source will lose credibility and the message will be rejected. This phenomenon has been observed in the government's earlier over-sensationalized fear-inducing messages concerning marijuana. For this reason, messages which do not advocate actions which are realistic and achievable are not likely to succeed. "If you drink, don't drive" is an example of a message which most people ignored on the basis of their own experience, having found that a drink during the evening did not seriously impair their ability to drive home later.

Presentation of Warnings

Nearly all of the experts consulted stated that warnings are most effective when the message conveyed is concise and clear, uncluttered by conflicting information from other credible sources, and supported by a broad-based and intensive public awareness campaign. An example of such a campaign is the National Poison Center Network's efforts to prevent accidental childhood poisonings through a community-oriented educational program using the frowning "Mr. Yuk" poison warning symbol as a logo. The educational campaign uses various mediums to reach the community, including posters and broadcast public service announcements. The message is two-fold: poisons with "Mr. Yuk" labels should be kept out of reach of children, and poison control information centers can answer questions and relay treatment information that may save a trip to the emergency room and possibly a child's

life. Studies conducted by the NPCN have shown the program to be successful in those cities where it has been tried (9). Research also shows that letter size, color, and use of graphics are important factors in determining how well a message is conveyed (3). The use of symbols rather than words can ensure that individuals who are illiterate or non-English speaking are more able to receive the message.

Cigarette Warning Labels

The Departments reviewed carefully the experience available on government initiated warning labels. Because of the government's extensive experience with regard to warnings on cigarette packages, the Departments gave careful attention to studies of their effectiveness.

Overall per capita cigarette consumption in the United States has declined significantly since 1964. On three occasions between 1950 and 1975 declines have been particularly marked. Each of these decreases occurred following release of information regarding the negative consequences of smoking (6). The first of these decreases, in 1953-1954, was preceded by several reports of adverse health effects of smoking in medical journals (Journal of the American Medical Association and Cancer Research), and in the popular press. There was a second, short-lived decrease following the release of the 1964 Surgeon General's Report on smoking. However, per capita consumption increased again in 1965 and 1966, but to a level still below that prior to the Surgeon General's report. A third major decline occurred in 1968-1970, possibly related to the combination of the warning labels on cigarette packages, the disclosure of tar and nicotine levels in ads, major educational efforts and anti-smoking commercials that appeared on television as a result of the Federal Communication Commission's fairness doctrine requiring the broadcast of anti-smoking messages to balance the cigarette commercials.

Since that time, the warning on cigarette packs has been strengthened (1970), cigarette advertising has been banned from television (1971), cigarette ads began to carry the same warning as the packages, and eight Surgeon General's reports on the health hazards of smoking have been issued. Numerous public education efforts designed to increase the public's knowledge of the health hazards of smoking have also been undertaken. However, millions of Americans continue to smoke despite these educational efforts.

Nonetheless, these communications efforts have had a positive impact. The level of public belief that smoking has harmful effects has increased in recent years. In 1966, the percent of American adults strongly agreeing with the statement, "Smoking is harmful to your health", was 50 percent; by 1970, it was 70 percent; by 1978, 73 percent. In 1978, an additional 17 percent "mildly agree," so there is 90 percent general public awareness of the smoking and disease link (6).

A 1979 survey by the National Center for Health Statistics indicates that the percentage of Americans who smoke (33.2 percent) is lower than it has been at any time in 30 years. Also, 90 percent of smokers have switched to filtered cigarettes and many to lower tar/nicotine cigarettes.

Although smoking levels have declined and public awareness of the health hazards has increased, the Departments concluded after reviewing available studies that it is impossible at this time to isolate the impact of any specific communication technique on smoking behavior including the cigarette warning label on the cigarette package (1). While the cigarette warning label has undoubtedly contributed to changes in health beliefs and smoking behavior, small-scale studies of the effectiveness of various anti-smoking interventions indicate that a health warning by itself is insufficient to change behavior (6). This is consistent with recent communications research, which has revealed that the relationship between behavior modification and changes in personal beliefs is considerably more complex than was previously thought. While increased levels of knowledge concerning health dangers may lead to changes in behavior, it does not always do so.

Therefore, the precise contribution of the present cigarette warning label on cigarette packages separate from other educational efforts is unclear. The controversy originally surrounding the decision to label cigarette packages with a health warning generated a great deal of discussion, debate and media commentary, and thus received public attention. However, as the present label became an accepted part of the cigarette package, this impact seems to have diminished.

Saccharin Warning Labels

Studies were also conducted to determine the effect of the saccharin warning (10). In February 1978, the Food and Drug Administration required retail establishments selling products containing saccharin to prominently display notices warning consumers about the association between saccharin and cancer in laboratory animals. In addition, manufacturers were required to place warning labels on the principal display panels for diet soft drinks.

To determine if these warnings affected diet soft drink sales, the government initiated a nationwide survey of 800 grocery stores (10). In all grocery stores surveyed, both regular and diet soft drink sales grew during the period studied. However, diet soft drink sales grew at below-average rates in stores in high-income and highly educated neighborhoods, in contrast with above-average sales growth rates in stores in lower-income and lower-educated neighborhoods. Differential price trends between regular and diet soft drinks were analyzed and shown not to be a factor influencing respective growth rates. As with cigarettes, however, researchers could not conclude what caused the changes in sales trends.

The overall impact of the saccharin warning undoubtedly was lessened by public confusion resulting from diverse, often conflicting media messages and the lack of a sustained, major information campaign conveying the research evidence linking saccharin and cancer in laboratory animals.

Warning Labels for Alcoholic Beverages

Currently, there are no general or specific warning labels on alcoholic beverages. There has been great controversy, even within the government, about previous efforts to require such labeling. Legal authority to require health hazard warning labels on alcoholic beverages rests with the Treasury Department, although such a warning may also be mandated by Congress.

Any proposal to require warning labels on alcoholic beverages is certain to create controversy which, in itself, would serve to reach large portions of the population with a health message. Even though labels alone are a communication effort, the Departments considered them as part of an overall campaign to inform the public of alcohol-related health hazards. General and specific warning labels were considered.

A general warning label on alcoholic beverages such as "Alcohol may be harmful to your health" would not convey new information to most of the public. Because specific health hazard warning labels may be more effective in conveying new and detailed information than general warning labels, several specific warning labels were considered. Particular attention was given to a warning label dealing with risks to the fetus of alcohol use during pregnancy. The purpose of such a communication would be to decrease the incidence of FAS and other alcohol related birth defects. Women of childbearing age are thought to be particularly susceptible to a message concerning the health of their unborn child. A warning label would alert the family and friends of pregnant women, as well as the women themselves, helping to develop a support system for the short-term behavior change required. A warning label directed toward alcohol consumption during pregnancy may fit some of the conditions under which such labels tend to be effective -- the threat to health is unequivocal, will be manifested relatively quickly, and requires only a short-term behavior change.

Despite these considerations, the Departments do not recommend warning labels directed toward FAS risks. The decision not to recommend warning labels was based on several factors:

- A pregnant woman or women in childbearing years confront multiple hazards to the safe completion of pregnancy. Among these are cigarette smoking, alcohol consumption, excessive amounts of caffein and inadequate diet. A strategy based on individual warnings directed toward each risk may simply have the effect of overwhelming the woman and her family with prohibitions. If "everything" appears to be harmful, some may adopt a fatalistic view and continue unsafe habits or lifestyles. In our judgment, such information can be more successfully conveyed through a public information campaign covering all significant risks to pregnancy rather than through a labeling effort directed toward the single risk of alcohol consumption, with corollary efforts singling out smoking and caffein.

- The nature of warning labels requires that the message relayed by them be simple and concise. In this instance, although no known safe level of alcohol has been determined for pregnant women, we cannot prove conclusively that moderate or intermittent consumption has long-term harmful effects. Moderate consumption has, however, been associated with higher rates of spontaneous abortion. The factual information necessary to be relayed through a warning label directed toward pregnant women is "Alcohol consumed during pregnancy can be a risk factor for the health of the child. Risk increases with the amount consumed. Excessive use can cause birth defects". This statement implies, but does not state directly, that there is no known safe

level of alcohol intake for pregnant women. However, given the nature of the available scientific evidence, a stronger or more explicit statement is not defensible at this time.

- A number of experts consulted warned that singling out a specific health issue such as FAS for a warning label may cause consumers to discount the importance of other significant alcohol related health hazards. Women's alcoholism groups consulted supported the use of warning labels to alert the public to the full range of alcohol health hazards but felt that women should not be singled out and thus, in their view, stigmatized, by warning only for FAS and other pregnancy-related risks.

Given these considerations it appears that the risks may be too complex to communicate on a label.

Labeling of alcoholic beverages with warnings about alcohol-drug interactions was also considered. The population of alcohol users to whom this message would be directed, however, is much less specific than the population of drug consumers, and the Departments felt that efforts should be directed to the drug consuming population through drug labeling, patient package inserts and other communication techniques.

Labeling alcoholic beverages with a series of specific health hazard warnings (rotating labels) was also considered as a possible method to convey a large number of specific health warnings to the alcohol-consuming public. The variation in labeling might maintain the consumer's interest about specific warnings. However, many alcoholic beverages have a long shelf life, and ingredients and alcohol content vary from brand to brand. Therefore, the Departments believe rotating labels for alcoholic beverages would confuse the public--causing them to believe that one particular brand (for example with 50 percent alcohol) might cause alcoholism while another product (with 12 percent alcohol) might cause birth defects, and so on. Also, such a requirement would pose potentially difficult administrative and enforcement problems, especially affecting imported products.

Conclusions Regarding Alcohol Warning Labels

After concluding the consultation process, reading communications literature and reviewing the aforementioned government experience with health warning labels, the Departments agreed that it would be premature to recommend health warning labels for alcoholic beverages at this time.

The judgment was based on the following considerations:

- Although both Departments believe the problems of alcoholism and other alcohol-related health hazards to be an extremely significant public health problem, it is not clear at this time that the risks associated with alcoholic beverages could be effectively communicated through labeling. A difficulty stems from the fact that it has not been established that moderate alcohol consumption is hazardous for most alcohol consumers. Therefore, unlike cigarettes, it might not be convincing to the general public to state "alcohol may be hazardous to your health." The issue is further complicated by the fact that health risks related to alcoholic beverages are quite different for specific population sub-groups -- risks assocated with drinking by teenagers and by pregnant women are unlike those for the general population. Beverage labels may not be a very efficient means of reaching special target populations with messages which are not directly relevant to the majority of purchasers of the product labeled. The Departments agreed after considering the complexity and difficulty of conveying the indicated messages through labels to try other methods of communicating these risks at this time. Such an approach is consistent with the advice given by various of our communications consultants that affirmative and complete messages are often more effective than those simply stressing prohibitions.

- In addition, both Departments were concerned that we not over-use one of the government's most important forms of health alert -- a general health hazard warning label -- if it is possible to communicate the information adequately through other means. If, as a number of communications experts advise, the public is becoming jaded over government warnings, the government should use health hazard warning labels with caution.

However, both Departments agree that the following steps will be taken:

- Communication strategies which are recommended in the Report will be carefully monitored to follow their effectiveness in educating the public regarding the health risks of alcoholic beverages.

- If, in the future, it is clear other methods of informing have not been adequate and there is evidence that warning labels could make a significant contribution to the public's understanding of alcohol hazards, Congress should consider a requirement of warning labels for selected alcohol-related risks. We are not now prepared to recommend this course of action.

Public Information Campaign

Another way to provide health information about alcohol-related hazards can be through multi-faceted information campaigns sponsored either by government, industry or private organizations.

Target Groups for Public Information Campaigns

During the consultation process, communication experts emphasized that, in order to achieve maximum impact, a public information program must be tailored to address target groups within the general population having particularly acute needs for specialized alcohol-health messages. In response to their advice, the Departments believe that targeted groups should be identified for each of the five problem areas. Each problem area should be analyzed to assure accurate audience segmentation. The general public should be included only as a target group for those alcohol messages which address issues of particularly broad interest and importance and which build support for intervention to alleviate destructive drinking patterns. The following list illustrates the types of groups that might be singled out for each message.

- Fetal Alcohol Syndrome and Other Alcohol Related Birth Defects. Potential parents; health care providers; educators; women who drink during pregnancy and alcoholic women.

- Alcoholism. Health care professionals; and professional helpers (clergy, counselors, social workers, etc.)

- Major Medical Consequences. General public; heavy drinkers; health care professionals; and professional helpers.

- Accidential Death and Injury The general public; employers in retail establishments selling alcoholic beverages; new drivers; employers; employees; law enforcement personnel; youth; sports participants and professional helpers.

- Alcohol-Drug Interactions. Health care professionals; alcohol and drug consumers; and educators.

The groups intended for targeting should be a prime consideration when designing a message and selecting an appropriate communications technique. For example, radio may be more cost effective in reaching a 13-18 year-old audience than television. Radio advertising is considerably less expensive than television, and radio stations are often formated specifically to carry music and other programming that appeals to a teenage audience. Minorities can be reached much more effectively if messages are culturally relevant and communications media are appropriate.

Regardless of the target groups to be addressed, the Departments have concluded from studies of past campaigns that it is important to build strong support for campaign objectives among community-level leaders, civic organizations, religious groups, and the like, all of whom can participate in developing and executing auxiliary local programs to strengthen the overall effort.

Slogan and Logo

An intensive alcohol information campaign built around a distinctive theme could be effectively drawn together by a logo or slogan. Such a logo and/or slogan could draw attention to and constantly reinforce information concerning all the specific health problem areas and could unify and thereby reinforce many elements of the various private and governmental campaigns. Symbols such as "Uncle Sam" for recruiting or "Smokey the Bear" for fire prevention, for example, were developed to serve as a visual "shorthand" reminder of more complex messages developed in auxiliary print materials. Likewise, slogans which summarize the theme, such as the anti-litter "Every Litter Bit Hurts" or "Pitch In," serve a similar purpose. Whether themes or symbols are appropriate to an alcohol campaign will depend upon how audiences are segmented and whether different target groups can be reached by a single unifying slogan or logo.

Public Service Messages

The Departments view print and broadcast announcements as an important tool in a broad, multi-faceted public information campaign designed to promote healthy practices. Advertising can help to focus attention on the campaign itself, point to sources of information and raise awareness of the issues involved -- in the present case, health hazards related to alcohol abuse. In the following discussion, therefore, it should be remembered that such activities are viewed as part of broader public education efforts.

Both the government and some industry members have committed funds to the production of public service announcements (PSA's) about alcohol. Yet the government PSA's are seldom aired in prime time. Industry, however, has had more success. The Distilled Spirits Council of the U.S. (DISCUS) spent approximately $4 million in 1979 on cooperative efforts with various groups, such as the Education Commission of the States and the National Football League to produce public service-type ads. Because of the multiple sponsors, the ads have been aired in prime time and particularly during NFL televised games.

Some private health organizations and alcoholic beverage industry associations have also used paid and public service advertising in newspapers and magazines to convey alcohol-related messages.

In addition, several individual distillers have produced and placed ads offering a wide range of advice on sensible drinking practices, particularly directed toward drivers, youth, party goers, and hosts and hostesses. Some distillers have also developed paid product advertising which incorporates a moderation message.

Nevertheless, public exposure to public service announcements is minimal compared to the impact of advertising to promote particular brands of alcohol, as noted in the introduction to this section.

Regulation of Advertising

Government Regulation

In 1933, Congress recognized the importance of regulating advertisements relating to alcohol when it included advertising as a section of the Federal Alcohol Administration Act (FAA Act)(5). The Bureau of Alcohol, Tobacco and Firearms (BATF) plans to issue proposed advertising regulations (Notice No. 313, 43 FR 54266, Nov. 21, 1978), which will address a wide range of issues such as setting standards for the use of the term "natural" and the use of athletes to promote alcoholic beverages. The Federal Trade Commission also exercises jurisdiction over alcohol beverage advertising and may bar acts or practices it deems to be unfair or deceptive.

Non-Government Regulation

Some industry members have taken significant steps to regulate their product advertising voluntarily. Both members and nonmembers of the Distilled Spirits Council of the United States (DISCUS) have voluntarily complied with an industry-wide ban on distilled spirits advertising on radio since 1936 and television since 1946. This ban, which appears in the DISCUS advertising code, is also reflected in the National Association of Broadcasters' radio and TV codes. There is no similar ban on beer and wine advertising in the broadcast media. Some other nations have totally banned or severely limited the advertisement of all alcoholic beverages in broadcast media. These nations include France, Norway, Sweden, Finland, and several of the Provinces of Canada.

The Wine Institute's Code of Advertising Standards (1978) emphasizes the use of wine at meals, requiring that where ads show wine served, there shall be food. The code discourages wine ads appealing to youth by prohibiting the use of their heroes, and sport celebrities, past or present. No models or personalities used in ads should appear to be under 25 years of age. The code even suggests that ads not be connected with programs showing inappropriate use of alcohol (13).

The U.S. Brewers Association (USBA) is currently revising its code of advertising. Past editions of the code have stated that ads should not appeal to youth, an important goal because beer is the drink of preference for youth (8). The code's present edition prohibits ads showing prominent athletes, although former athletes can appear. It prohibits linking beer with any activities, such as driving, which require a high degree of alertness. These standards are not always followed.

RECOMMENDATIONS

The abuse of alcohol is a major health problem in the U.S., causing premature death, illness, and disability. Of particular concern is the widespread use of alcohol among the nation's youth. The Departments believe that, while the problems of alcohol abuse are substantial, many are preventable. We note that the Surgeon General's report, "Healthy People," released in 1979, identified alcohol abuse as a major U.S. health prevention challenge.

While the public generally knows that alcohol abuse can cause serious health problems for the abuser and individuals who come in contact with him or her, the Departments do not believe that the public is sufficiently aware of all of the specific short and long term effects of alcohol on the health and well-being of different individuals. The Departments believe that a heightened awareness of these specifics would contribute to a lessening of the health problems related to alcohol.

The Departments believe that both industry and government have a responsibility to alert the public to the problems that may arise from alcohol misuse. The Departments also feel strongly that the overall success of any effort to inform the public depends to a great extent on active industry participation and support. Therefore, the recommendations are addressed to both government and industry.

The recommendations are organized into three broad categories:

- Providing information to the general public about the health effects of alcohol.
- Providing information to the consumer about the contents of alcoholic beverages.
- Providing information to health care providers and other helping professions about alcohol-related health hazards.

Providing Information on Health Effects of Alcohol

The Departments found that numerous information gaps and substantial misinformation relating to alcohol use exist among the American public. People are unaware of the effect rapid consumption can have on the body, the nature of the links between drinking and cancer or birth defects, and problems that can arise if alcohol is consumed with any one of a wide range of drugs. People generally have very limited knowledge about alcoholism - what it is and what resources are available for counseling and treatment. To bring about an increased level of public awareness the Departments recommend:

1. Government, industry and private organizations should develop and conduct a broad-based, diverse and highly visible public information campaign on alcohol-related health problems. To the extent possible, the combined campaign should be built upon a common strategy.

Such a common strategy could for example identify the specific changes in use or consumption patterns the campaign seeks and the information and motivation needed by the consumer to achieve these changes.

The message of the campaign should be positive and constructive, encouraging each individual to consider his/her own situation before drinking. It should recognize that, for some people, the responsible or healthy decision is to abstain. For others, this would not be necessary.

Those developing the campaign should consult with experts in the communications, public relations and advertising fields. The campaign strategy should encompass a wide range of media, including but not limited to television, radio, print, brochures, display and point of sale advertising.

It is recommended that industry coordinate its campaign efforts through a centralized body, such as the already-established Beverage Alcohol Information Council, or a similar organization of its choice.

Although the Departments do not think that participation by individual industry members should be mandatory, the Departments will monitor the campaign to determine the extent of industry cooperation and, if appropriate, report these findings with recommendations for additional action to Congress.

2. In consultation with government, industry should develop an effective slogan and/or logo, or a family of related slogans or logos, to lend verbal or visual identity to the elements of the campaign. Alcoholic beverage producers should voluntarily use the slogan and/or logo in consumer product information.

The Departments recommend that industry members coordinate with Treasury personnel, who will consult with HHS in this effort. Industry should test market a number of slogans or logos to determine which is most effective and that there are no unintended consequences.

Industry should incorporate the slogan or logo on alcohol beverage container packages, such as six-packs, and in tag lines for a substantial portion of print and broadcast advertising. Industry should insure that all such materials are distributed at points of purchase, i.e. retail establishments, and that posters, coasters and other hand-outs featuring the slogan or logo are prominently displayed. Also, the industry working with government and voluntary organizations should develop brochures which incorporate the theme and give useful information regarding alcohol use. These should be distributed at point of sale and other locations, including racks in grocery stores, health fairs and doctors' offices.

The government will monitor industry participation. ATF will also monitor advertising and informational materials based on the strategy to ensure that it is not used in a context that is false or misleading. ATF will consult with HHS with regard to the scientific accuracy of the information presented.

3. HHS will expand its current efforts to inform and educate the public regarding major alcohol-related health hazards; Treasury will continue its current efforts to inform and educate the public regarding effects of alcohol consumption during pregnancy and continue to work with industry to monitor and encourage the BAIC Fetal Alcohol Awareness Campaign.

HHS and Treasury will also continue collaboration with appropriate State and local agencies to inform and educate the public regarding alcohol-related health hazards. HHS will encourage private sector organizations having a direct interest in reducing alcohol-related health hazards -- for example, major employers, insurance carriers, and labor unions -- to participate in efforts to inform and educate the public regarding these hazards.

4. HHS will work with the Department of Education, voluntary groups, State agencies and industry groups concerned with alcohol education to increase the use of model alcohol curricula on the local level.

Effective alcohol education programs, directed at various age groups, could increase student awareness of potential alcohol-related problems. This is one target group of a national HHS education campaign now being developed. Such programs may make individuals more receptive to related messages in the future and thus lead to increased general public awareness.

5. HHS will develop a public information program aimed at women who are pregnant or plan to become pregnant with advice on how to protect the health of their children.

The new "Healthy Mothers" program will be a long term campaign to reach expectant mothers and their families with positive advice on how to care for themselves before, during, and after pregnancy and how to assure the best care for children in their early and developing years. This campaign, which will approach the subject from a positive rather than negative warning aspect, will be an "umbrella" program, cutting across lines to supplement and support categorical approaches focused on specific subjects. It will promote good nutrition, early and continuing prenatal care, and avoidance of smoking, alcohol, caffeine and harmful drugs.

6. HHS will encourage the accurate portrayal of alcohol-related health hazards in the print and broadcast media.

The National Institute on Alcohol Abuse and Alcoholism provides information and technical assistance to print and broadcast media to help assure the accurate portrayal of alcohol-related problems and alcohol use in articles and script development. Accurate portrayal in such a medium as television is extremely valuable --- it reaches a mass, heterogeneous audience in prime time in an entertainment mode. This service will be promoted to writers and producers in the media.

7. Treasury will encourage the alcohol beverage industry to review the impact of its advertising practices on alcohol-related health hazards and revise its voluntary codes of advertising as appropriate. The question of whether the Congress should place additional restrictions on alcohol beverage advertising should continue to be considered.

The Treasury Department will look with particular interest at the new revised code being developed by the U.S. Brewers Association (USBA) and at any new codes developed by producers of malt beverages who are not members of USBA or wine producers not members of the Wine Institute. The Department will also consider the general level of compliance with these voluntary codes. If, after a reasonable period of time, there are still serious problems, the government will consider if legislative recommendations should be submitted to the Congress.

8. HHS and Treasury support the National Highway Traffic Safety Administration programs to discourage driving while under the influence of alcohol.

Traffic accidents are the greatest cause of violent death in the United States; approximately one third of the deaths resulting from traffic accidents are related to alcohol consumption. The Departments support pending Federal legislation which would require the establishment of a comprehensive alcohol-traffic safety program in each State aimed at discouraging driving while under the influence of alcohol (as a condition for receipt of Federal highway safety funds).

Providing Clearer Information on Alcohol Content

The public, in general, does not understand how much alcohol is in a specific product and how products compare with each other. Some individuals incorrectly believe an average serving of beer or wine contains less alcohol than the average drink of distilled spirits. In fact, one 12 oz. can of beer (4.5% by volume), one 5 oz. glass of wine (12% by volume), and one highball with 1.5 oz. of 80 proof liquor (40% by volume) are approximately equal in alcoholic content and intoxicating qualities. In addition, the alcohol content is sometimes presented in a manner that the public does not understand, such as by "weight" or by "proof." At present, the FAA Act prohibits the alcohol content of beer or other malt beverages to be shown on labels unless it is required to appear by State law. Labels for wine must indicate alcohol content in percent by volume, except that wines containing 14 percent or less alcohol by volume need not show alcohol content if the label bears the designation "Table Wine" or "Light Wine." Federal regulations require distilled spirits to state alcohol content by proof, or for cordials or specialties, by percent by volume.

The Departments are convinced that public awareness and understanding would be enhanced if the alcohol content were consistently and clearly indicated on all domestic and imported alcoholic beverages. The consumer could then, at least, comparatively evaluate the products. The Departments therefore recommend that an alcohol content statement indicating percent by volume be required for all alcoholic beverages.

1. Congress should amend the FAA Act to require malt beverages to be labeled to disclose the alcohol content as a percent by volume.

The FAA Act exempts malt beverages from Federal labeling regulations unless the State where it is sold has adopted those regulations or has similar requirements. However the Act prohibits statements of alcohol content from appearing on malt beverages unless specifically required by the State in which it is sold. Some States have decided to adopt the FAA Act requirements which prohibit the indication of alcohol content on malt beverages. Other States may, for example, prescribe that the alcohol content be indicated by percent of alcohol by weight. By indicating the alcohol content by weight, the public could assume there is less alcohol in beer. For example, 3.2% by weight beer typically contains 4% alcohol by volume. By requiring the alcohol content to appear on labels of malt beverages in one format (percent by volume) the consumer could easily compare the different products.

2. Require distilled spirits to be labeled for alcohol content as a percent by volume.

Federal regulations require that distilled spirits indicate alcohol content by proof, except cordials and specialty products which may show it as proof or percent by volume. We doubt, however, that all consumers know that proof is twice the alcohol content by volume.

There are two alternative ways to require that distilled spirits are labeled consistently with wine: (1) amend the law to require distilled spirits to show the alcohol content as a percent by volume rather than proof, or (2) change BATF regulations to require that percent by volume appears in addition to the proof statement. The first alternative would necessitate extensive revamping of relevant laws and regulations, since the present Federal alcohol tax structure is based on proof level. Consultations with industry are essential to determine potential costs, administrative burdens and potential resource demands on Treasury. Treasury needs to further evaluate the alternatives and their interrelationships before making a specific recommendation as to the best approach.

3. Congress should amend the FAA Act to require all wines to be labeled to disclose the alcohol content as a percent by volume.

The FAA Act provides that statements of alcoholic content shall be required only for wines containing more than 14% alcohol by volume. Federal regulations on wine require the alcohol content to be stated in percent by volume, except that wines containing 14 percent or less alcohol by volume may use the term "Table Wine" or "Light Wine" in lieu of stating the alcohol content. We doubt that consumers are aware of the regulatory definition of "Table Wine" or "Light Wine" and thus, we believe that they would be unaware of the alcohol content of products so labeled.

Provide Information to the Public through Health Professionals

Health professionals should be a primary source of information about health hazards associated with alcohol. Yet, during the Departmental

consultations, physicians confirmed that most lack training regarding health consequences of alcohol use and many are unaware of the recent research findings about the five major health hazards discussed in this Report. The lack of current information was particularly troublesome respecting fetal alcohol effects. Consumers overwhelmingly confirmed that their physicians are generally not a useful source of information regarding alcohol use. Yet, the potential for impact among physicians and health professionals is great. Health professionals are in the best position to know a patient's general medical condition -- whether the patient is abusing alcohol or could be harmed by alcohol. Screening devices -- questions designed to indicate current or potential abuse -- should be a routine part of general patient care. The physician's office, clinic or pharmacy are logical distribution points for patient-oriented brochures with alcohol and health information. Keeping health professionals apprised of recent developments in alcohol-associated health hazards would allow dissemination of the most up-to-date information to their patients. HHS will consult further with the American College of Obstetrics and Gynecology to review the most recent evidence on the effects of moderate alcohol consumption during pregnancy and to consider how the College might wish to advise its members on communicating this information to patients. The Department will also use such publications as the Morbidity and Mortality Weekly Report to communicate to professionals the latest knowledge about the consequences of alcohol consumption, especially during pregnancy. The Departments recommend the following action:

1. The Surgeon General will issue an advisory on the major health problems discussed in this Report.

The Surgeon General's Report issued in 1964 on smoking had a significant impact on the smoking habits of Americans. A similar report on alcohol problems could contribute to a lessening of alcohol-related problems.

2. HHS will encourage States to require that health care and other appropriate professionals seeking State licenses and recertification demonstrate their knowledge of alcohol-related health hazards.

This requirement by certification and recertification boards would have the effect of encouraging schools for health care and other professionals to incorporate alcohol education into their curricula.

3. HHS will increase its support for development of curricula about the health consequences of alcohol consumption, and will encourage incorporation of such curricula into the basic professional education for physicians, nurses, pharmacists, social workers, and other health care delivery system professionals.

Physicans are not routinely trained to recognize and treat the health consequences of alcohol consumption. According to the Association of American Medical Colleges (AAMC), most schools offer an elective course on alcoholism and medicine. However, a survey by AAMC of 1979 graduates showed that only 2.2% of respondents chose to take that elective. Thorough treatment of alcoholism and other alcohol-related health hazards should be part of the standard core curricula in health professions training.

4. HHS will encourage the development of more sophisticated social and medical screening techniques to improve identification of individuals at high risk for alcohol-related health hazards.

Some screening devices already exist; other devices need to be developed. Their use ought to be encouraged.

5. FDA will intensify its efforts in reviewing and updating prescription and over-the-counter drug labeling to inform the health care professional and patient about the potential of alcohol-drug interactions.

FDA publications and professional drug labeling are major sources of information for health professionals. As FDA finds potential alcohol-drug interaction hazards, these sources will be used to alert users.

6. FDA will continue other informational activities.

FDA will issue an updated article on the effects of alcohol consumption on pregnancy outcome in the FDA Drug Bulletin.

APPENDICES

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

Notice No. 80-4

To all concerned:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

DEPARTMENT OF THE TREASURY

[Notice 80-4]

Health Hazards Related to Alcoholic Consumption; Information Required To Furnish a Joint Agency Report to the President and the Congress as Required by Pub. L. 96-180

AGENCIES: Department of Health, Education, and Welfare and Department of the Treasury.

ACTION: Notice with invitation to comment.

SUMMARY: Congress has instructed the Department of Health, Education, and Welfare and the Department of the Treasury to prepare jointly a report for the President and the Congress by June 1, 1980. This report is in response to Public Law (Pub. L.) 96-180, the "Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act Amendments of 1979." The report will address the following issues:

(1) The extent and nature of birth defects associated with alcohol consumption by pregnant women;

(2) The extent and nature of other health hazards associated with alcoholic beverages; and

(3) The actions which should be taken by the Federal government under the Federal Alcohol Administration Act and the Federal Food, Drug, and Cosmetic Act with respect to informing the general public of such health hazards.

DATE: Written comments must be received by March 27, 1980.

FOR FURTHER INFORMATION CONTACT: Michael Dressler, Special Operations Branch, Bureau of Alcohol, Tobacco and Firearms, [202] 566-7591.

SUPPLEMENTARY INFORMATION:

I. Public Participation

In order to prepare a comprehensive report for the President and the Congress, the Assistant Secretary for Health of the Department of Health, Education, and Welfare and the Assistant Secretary for Enforcement and Operations of the Department of the Treasury are requesting all interested parties to submit, in writing, brief comments summarizing views or opinions on health hazards related to alcohol consumption and actions that should be taken to warn the public of these health hazards. Materials submitted in response to the Bureau of Alcohol, Tobacco and Firearms (ATF) Notice on Fetal Alcohol Syndrome, published January 16, 1978, or the Senate Subcommittee hearings on Alcohol Labeling and Fetal Alcohol Syndrome on January 31, 1978 or the hearings on Health Warnings for Alcoholic Beverages and Related Issues on September 14, 1979 should not be submitted. All of these comments and research data are currently being reviewed by the staffs of HEW and Treasury.

It is requested that the comments be in a summary format. The summary should identify the name of the commenter and organization represented. If you believe there are relatively recent research findings not previously presented, you may submit summaries of these studies which include the individuals or group conducting the research, approximate length, date completed or date commenced if not completed, results of the study and name of professional journal(s) in which the study has been published.

Of particular interest would be information relating to:

(1) On-going or recently completed studies on Fetal Alcohol Syndrome.

(2) Any current research data on health problems associated with alcoholic beverage consumption.

(3) Any current research data on health problems associated with food or drugs containing alcohol. (Example: cough syrup or food extracts).

(4) Current research data on health problems associated with alcohol consumption in conjunction with the use of drugs. (Example: painkilling drugs, tranquilizers, etc.).

(5) Studies which measure the effectiveness of different approaches to alerting the public regarding health hazards associated with a product.

ADDRESS: Forward written comments, in duplicate, to: Chief, Trade and Consumer Affairs Division, Bureau of Alcohol, Tobacco and Firearms, 1200 Pennsylvania Avenue NW., P.O. Box 385, Washington, D.C. 20044.

Approved: February 22, 1980.

Richard J. Davis,

Assistant Secretary (Enforcement and Operations).

Julius B. Richmond,

Assistant Secretary for Health.

[FR Doc. 80-6147 Filed 2-25-80; 11:33 am]

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SUMMARY OF PAST AND PRESENT ACTIVITIES

Government, industry, and voluntary organizations have devoted considerable resources to addressing alcohol problems. This appendix discusses past and present efforts in the five major problem areas and, as Congress requested, the State of Utah's experience with warning posters.

* Fetal alcohol syndrome (FAS) and other birth defects.

The federal government, the alcohol beverage industry, and private organizations already are participating in a public awareness campaign about FAS.

As part of that campaign, the National Institute on Alcohol Abuse and Alcoholism (NIAAA) is developing a mass media public education campaign which will include radio and TV public service announcements (PSAs) and print material directed at women and youth. Materials will be distributed through intermediary groups such as State alcoholism agencies and others which will promote further distribution of materials through physician's offices, health clinics, supermarkets, alcoholism agencies, and community groups. NIAAA has also provided technical information to assist health care providers in diagnosis and treatment; made a substantial commitment to research; and provided grant support for demonstration project and educational programs.

The Food and Drug Administration (FDA) has produced several articles and a slide show for distribution and has featured FAS in an issue of its Drug Bulletin, which reaches more than a million health care providers. The October 1977 issue contained an article summarizing the latest scientific data about FAS. In addition, FDA Consumer Affairs Officers in 35 major cities were provided text for a column about FAS to be placed in small, local papers under their by-lines.

The Bureau of Alcohol, Tobacco and Firearms (BATF) has produced a TV public service announcement aimed at the middle class woman. An illustrated booklet aimed at young people is being distributed in three versions (English, Spanish, and English for American Indians). Thirteen states ordered the booklets for distribution through their retail liquor stores. BATF has also supervised the Beverage Alcohol Information Council (BAIC) campaign.

The BAIC, a consortium of ten major trade groups in the alcoholic beverage industry, was created especially to carry on an FAS campaign at the request of the Treasury Department (BATF Notice No. 318). The BAIC campaign includes TV public service announcements aimed at young women (these are soon to be aired), magazine ads, posters for display at point of sale and health clinics, mass mailings of newsletters to physicians by Raleigh Hills Foundation and Harvard Medical School, press releases, materials for use in producing feature stories about FAS, and funding for curricula development for secondary schools in cooperation with the Education Commission of the States. Boston University Medical School received BAIC funds to develop a Fetal Alcohol Education Program to aid physicians in identifying and preventing birth defects. The Treasury Department would like to see development and test-marketing of point of sale materials.

The ten industry groups participating in the BAIC are:

Association of American Vintners

Distilled Spirits Council of the United States, Inc.

Independent American Whiskey Association

National Association of Beverage Importers, Inc.

National Beer Wholesalers' Association of America

National Licensed Beverage Association

National Liquor Stores Association, Inc.

United States Brewers Association, Inc.

Wine and Spirits Wholesalers of America, Inc.

Wine Institute

Several private organizations such as the March of Dimes the American Council on Alcoholism, and the National Council on Alcoholism have produced films, radio PSAs and brochures in English and Spanish.

Many states already have initiated or are planning FAS campaigns using the above materials or their own.

Utah test-marketed FAS warning signs and posters in two of the largest liquor stores in the State. When purchasers were surveyed, they stated that they were committed by the time they saw material at the point of purchase. PSAs and programs in schools were deemed more appropriate.

In Washington State, the Pregnancy and Health Program of the University of Washington has produced several brochures and PSAs. The brochures, alerting women of child-bearing age to a treatment and education program at the University, have been distributed in a variety of settings including state liquor stores. The University has noted a significant increas in inquiries to this program, part of which can be attributed to the brochures distributed in liquor stores.

* Alcoholism

The Federal government, as well as private and voluntary organizations, have oriented much of their prevention and treatment programs for alcohol-related problems toward alcohol dependence or alcoholism. In the early years of this effort, considerable emphasis was placed on recognizing alcohol dependence as a disease or illness in order to encourage the early detection, diagnosis, and treatment of alcoholism and to mobilize community resources in attacking this problem. Despite important gains in this area, this emphasis continues at the Federal level and in the private and voluntary sector.

In recent years, this focus on alcoholism or alcohol dependence has been expanded considerably, especially at the Federal level, to embrace problem drinking and a host of other alcohol-related problems where alcoholism may or

may not be present. These expanded programs do not diminish the emphasis on alcohol dependence in Federal, private or voluntary programs to prevent alcoholism through public information, education, early diagnosis, or other means.

* Major medical consequences

The Health Resources Administration, in conjunction with NIAAA, has developed a program which will provide support to Departments of Family Medicine to teach medical students about alcoholism and alcohol abuse.

NIAAA is also devoted to reaching health care professionals through the development of curriculum materials. The Institute has been responsible for making available materials of interest to physicians, nurses, physicians assistants, and nurse practitioners as well as the full range of health care professionals.

NIAAA, the National Institute of Mental Health, the National Institute on Drug Abuse (NIDA) and the Bureau of Community Health Services, Health Services Administration, have developed materials to teach Community Health Center (CHC) primary care personnel about the problems of alcohol, drug abuse, and mental health. The program will reach out to related primary care facilities where alcohol, drug abuse, and mental health services should be made available to the clients of CHCs.

NIAAA and NIDA have jointly sponsored and funded the career teacher program in alcohol and drug abuse. This program is designed to enable medical schools to provide training for medical students, nurses, and other health professionals in the problems of alcohol and drug abuse. Since the inception of the program in the early 1970 s, more than 60 institutions have received support.

* Accidental Death (Traffic and Other)

Numerous efforts have been made to prevent alcohol-related accidents, particularly those involving drinking and driving. Between 1970 and 1977, the Department of Transportation committed $88 million to Alcohol Safety Action Projects (ASAP) across the nation. In 1973, Education Commission of the States (with NIAAA funding) formed a Task Force on Responsible Decisions About Alcohol which became the springboard for several campaigns highlighting "responsible" approaches to alcohol use, sponsored both by industry and government.

In 1974, the National Highway Traffic Safety Administration (NHTSA) adopted as its national campaign slogan "Friends don t let friends drive drunk." This slogan, and the caring attitude it promotes, is designed to encourage people to intervene when they know they should, but may feel uncomfortable about doing so.

The NIAAA is currently developing a mass media campaign aimed at youth designed to assist in reducing drinking-driving problems. In addition, NIAAA will fund model programs in communities to reduce drinking-driving problems among young people.

The U.S. Brewers Association and the Distilled Spirits Council of the U.S. (DISCUS) are cooperating in safety programs on drinking and driving with NHTSA and the various states. DISCUS "Know Your Limits" campaign offers specific guidelines on consumption effects and calls for "sensible drinking." Private organizations such as the American Automobile Association and the National Safety Council have developed and distributed materials concerning drinking and driving. Many States and other organizations have conducted campaigns using the above materials on their own.

* Alcohol-drug Interactions

In June, 1979, as part of the H.E.W. Alcohol Initiative, an FDA Drug Bulletin and a Surgeon General s Advisory dealing with alcohol-drug interactions were sent to health professionals. The Alcohol Initiative also included publication of several articles in the FDA Consumer magazine about alcohol-drug interactions.

Professional drug labeling (package insert) is used by health professionals as a source of information, including health and alcohol-drug interaction warnings about prescription drugs. The same labeling information is found in the Physicians Desk Reference widely available to all health professionals. Professional labeling is regulated by the FDA. Professional labeling for drugs which interact with alcohol was reviewed in 1979 by FDA. Efforts were started to change labeling of drugs with inadequate warnings about alcohol-drug interactions. FDA had advised manufacturers that labeling of prescription drug products for which alcohol-drug interaction labeling was inadequate should be upgraded prior to the next printing of these products labeling.

FDA has proposed consumer-oriented labeling of prescription drugs (patient package inserts or PPIs) which would identify special warnings present in professional labeling to the consumer. In the cases of propoxyphene (Darvon) and Valium, PPIs were developed that particularly highlight the hazard of alcohol use with these products. The Darvon PPI is in use; the Valium PPI is being pre-tested.

Alcohol is present in many over the counter (OTC) and prescription preparations; the alcohol content is declared on the label for both prescription and OTC drugs. This labeling is beneficial to individuals on Antabuse therapy or other alcohol-withdrawal treatment programs. The FDA is not aware of any evidence showing that the alcohol in these products presents a problem in causing interaction with other drugs.

Labeling for OTC drug products is being reviewed for the FDA by panels of medical and scientific experts. As a result of this review, the panels recommended that two classes of drug products be labeled with warnings about possible interactions with alcohol. Documents have been prepared to require alcohol - drug interaction warnings for OTC cough and cold remedies and nighttime sleep-aid products containing antihistamine. Other OTC drug classes do not have such labeling because alcohol-drug interactions have not been known to occur.

General Warnings

Congress specifically asked the Departments to look at the experience of the State of Utah with warning posters. In 1977, Utah required by law that all liquor stores, and restaurants and private clubs serving alcoholic beverages display a poster stating:

> "WARNING: The consumption of alcoholic beverages purchased in this establishment may be hazardous to your health and the safety of others."

Mr. Dennis Kellen, Operations Manager of the Utah State Liquor Control Commission, states that the posters seem to have little effect in deterring purchases. They have, in fact, become the subject of humorous depictions, e.g. on t-shirts. Tourists and and college students request the posters as souvenirs.

Utah feels that their experience from test marketing FAS warning posters (see discussion in the above FAS section) also applies to the general warning poster. In surveys of customers in two of the state s largest liquor stores where the FAS posters were tested, a majority of purchasers commented that they were already committed to their purchase by the time they saw the posters. Mr. Kellen received reports that purchasers considered the posters inappropriate and laughable.

Mr. Kellen reported that the general warning poster as it now appears may actually stimulate liquor sales in restaurants by alerting patrons to the availability of liquor. Utah concluded that PSAs and educational programs would be more appropriate.

The American Council on Alcohol Problems, Inc., Des Moines, Iowa, has recently published a brochure, "What you need to know about alcohol for your health and safety." The brochure offers information on rapid consumption, impact on driving ability, threat of addiction, and impact on the fetus. It is being distributed with purchases in liquor stores in ten states so far. Although no evaluation has been conducted to date, the Council hopes that other states will distribute brochures in their liquor stores.

AUTHORITY UNDER THE FEDERAL ALCOHOL ADMINISTRATION ACT AND THE FEDERAL FOOD, DRUG, AND COSMETIC ACT TO REQUIRE HEALTH WARNINGS IN ALCOHOLIC BEVERAGE LABELING AND ADVERTISING

I. AUTHORITY UNDER THE FEDERAL ALCOHOL ADMINISTRATION ACT TO REQUIRE HEALTH WARNINGS IN LABELING AND ADVERTISING

This opinion addresses the question whether the Secretary of the Treasury has the authority to require health warnings in alcoholic beverage advertisements and labels. The warnings in question may concern both the possible dangers to unborn children caused by alcohol consumption by pregnant women and the effects of alcohol consumption on the drinker. This opinion concludes that while the Federal Alcohol Administration (FAA) Act contains no express statutory authority to require health warnings, such authority may -- subject to some doubt -- reasonably be inferred using established canons of judicial construction.

The FAA Act contains no express authority to require health warning statements in alcoholic beverage advertising and labeling. However, the Act authorizes the Secretary to prescribe regulations concerning alcoholic beverage advertising and labeling to carry out certain enumerated purposes. The most relevant of these are:

(1) Prohibiting deception of the consumer and statements likely to mislead him with regard to age, manufacturing processes, analyses, guarantees, and scientific or irrelevant matters;

(2) Providing the consumer with adequate information as to the identity and quality of the product and the alcoholic content thereof; and

(3) Prohibiting false, misleading, obscene, or indecent statements and those disparaging of a competitor's products. 27 U.S.C. §§ 205(e)(1), (2), and (4) and 205(f)(1), (2), and (4).

In addition, 27 U.S.C. § 205 provides with regard to the power of the Secretary to prescribe regulations:

> The Secretary of the Treasury shall give reasonable public notice, and afford to interested parties opportunity for hearing, prior to prescribing regulations to carry out the provisions of this section.

Where authority for a regulatory agency to take a particular action is not expressly granted by statute, courts will, nevertheless, infer such authority if it is reasonably related to the purposes of the statute. As was stated in Morrow v. Clayton, 326 F.2d 36, 44 (10th Cir. 1964):

> [I]t is a fundamental principle of administrative law that the powers of an administrative agency are not limited to those expressly granted by the statutes, but include, also, all of the powers that may fairly be implied therefrom.

Such implied power was found in Warner-Lambert Co. v. Federal Trade Commission, 562 F.2d 749 (D.C. Cir. 1977), cert. denied, 435 U.S. 950 (1978), which held that the FTC had the authority to require affirmative advertising under the Federal Trade Commission Act for purposes of correcting past misleading advertising. In that case the defendant was ordered to cease and desist from advertising that Listerine mouthwash prevents, cures, or alleviates the common cold and to indicate in future advertising that Listerine will not produce these effects. The court held that the FTC had the power to order corrective advertising even though the Federal Trade Commission Act, which authorizes the Commission to issue "cease and desist" orders against violators, does not expressly mention any other remedies.

Apparent from the statutory provisions cited above, Congress established general guidelines as to the advertising and labeling of alcoholic beverages and provided for the promulgation of regulations to implement these guidelines. In doing so Congress called for a flexible approach to labeling and advertising, allowing for timely response to changing needs. The Supreme Court viewed regulations as serving this purpose of flexibility in American Trucking Associations, Inc. v. United States, 344 U.S. 298, 309-310 (1953), in which it stated that it was not "a reasonable canon of interpretation that the draftmen of acts delegating agency powers, as a practical and realistic matter, can or do include specific consideration of every evil sought to be corrected."

In Thorpe v. Housing Authority of the City of Durham, 393 U.S. 268, 280-281 (1969), the Supreme Court articulated the standard against which an agency rule is to be tested:

> Since the Authority does not argue that the circular is proscribed by any constitutional provision other than the Due Process Clause, the only remaining inquiry is whether it is reasonably related to the purposes of the enabling legislation under which it was promulgated.

In that case, the court considered a circular issued by the Department of Housing and Urban Development pursuant to its power, under section 8 of the United States Housing Act of 1937, "from time to time [to] make, amend, and rescind such rules and regulations as may be necessary to carry out the provisions of this Act." The circular directed local housing authorities operating federally assisted projects, before instituting eviction proceedings, to inform the tenant of the reasons for eviction and to provide him an opportunity to reply or make such explanation as he may wish. Although the United States Housing Act under which the circular was promulgated contained no specific authority for the rule it announced, the court upheld it as reasonably related to one of the purposes expressed in another Federal housing law -- to provide a decent home for every American family lacking the financial means to obtain one without assistance.

To be sure, the "reasonable relation" standard articulated in Thorpe was set forth in response to a constitutional attack on the circular based on the Due Process Clause of the Fifth Amendment. However, in Mourning v. Family Publications Service, Inc., 411 U.S. 356, 369 (1973), the Supreme Court, quoting Thorpe, applied this same standard but without the constitutional link. In Mourning the court upheld a Federal Reserve Board regulation as reasonably related to section 121 of the Truth in Lending Act, which required merchants who regularly extended credit to disclose certain contract information to each person to whom consumer credit was extended and upon whom a finance charge was or might have been imposed. The challenged regulation provided that contract information had to be disclosed not only when a finance charge was or might have been imposed, but also when, pursuant to an agreement, the purchase was payable in more than four installments. The court found that the regulation served to prevent circumvention of the statute by merchants intent upon burying finance charges in the purchase price. See American Trucking Associations, Inc. v. United States, supra, where a similar prevention-of-circumvention theory was used to sustain a regulation for which there was no specific statutory authority.

A requirement that labels and advertisements carry a warning against alcohol consumption, particularly by pregnant women, is reasonably related to the purposes of 27 U.S.C. §§ 205(e) and (f), namely preventing consumer deception and providing needed information as to the identity and quality of the product purchased. That the FAA Act and implementing regulations on the labeling and advertising of alcoholic beverages are aimed at protecting consumers is beyond question. See Gibson Wine Co. v. Snyder, 95 F. Supp. 145, 146 (D.D.C. 1950), aff'd, 194 F.2d 329 (D.C. Cir. 1952). The statute's purposes are evident from its language, which authorizes the Secretary to prescribe labeling and advertising regulations for the following purposes: (1) to prohibit deception of the consumer and statements likely to mislead him, (2) to inform the consumer adequately about the identity and quality of the product, and (3) to prohibit false and misleading statements. The legislative history supports the notion of requiring alcoholic beverage producers to provide needed information to the consumer. The Senate Committee on Finance, which reported on H.R. 8870, 74th Congress, 1st Session, envisioned the following as the purpose of 27 U.S.C. §§ 205(e) and (f):

> The second class of unfair practices prohibited by the bill are those relating to false labeling and false advertising or labeling or advertising that is not adequately informative, to the end of affording the consumer adequate protection and of preventing unfair competition. (Emphasis added.) S. Rep. No. 1215, 74th Cong., 1st Sess. 7 (1935), "Federal Alcohol Control Act."

A requirement that a warning be included in alcoholic beverage labels and advertisements would enhance the consumer-protection purpose of 27 C.F.R. §§ 205(e) and (f) and serve the congressional intent of allowing for flexibility through regulation.

Of course, there are arguments against recognizing that authority exists under the FAA Act to require health warnings in advertisements and labels of alcoholic beverages. Two such arguments warrant consideration. The first is that the absence of express authority in the Act to require warnings indicates congressional intent that the Secretary of the Treasury have no such authority, especially since Congress has given other agencies express authority to require warning statements. For example, 15 U.S.C. § 52(a)(1) prohibits any "false advertisement" in food, drugs, devices, or cosmetics, and section 55(a)(1) makes the failure of an advertisement to reveal consequences which may result from use of the product a relevant consideration in determining whether an advertisement is false. In addition, the Federal Food, Drug, and Cosmetic Act states that in determining whether labeling or advertising is misleading, the extent to which it fails to reveal consequences which may result from use of the article should be taken into account, 21 U.S.C. § 321(n). Thus, FDA and FTC (with respect to food, drugs, cosmetics, and devices) have express authority for requiring warning statements and have not had to rely on broad legislative language.*

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* Congress has enacted legislation directly requiring specific warning statements with regard to saccharin (Saccharin Study and Labeling Act, Pub. L. No. 95-203), cigarettes (Public Health Cigarette Smoking Act, Pub. L. No. 91-222), and poisonous household substances (Poison Prevention Packaging Act of 1970, Pub. L. No. 91-601).

While an inference may be raised from the lack of a specific statutory provision to require health warnings, such an inference is not determinative of the issue.

The second argument against inferring authority under the FAA Act to require health warnings in advertising and labeling is that such inferred authority would not serve any of the following three purposes. It is for these purposes that courts traditionally have sanctioned agency action not expressly authorized by statute: (1) to prevent circumvention of a statute, (2) to fashion appropriate remedies, and (3) to carry out regulatory authority to achieve a broadly but explicitly stated goal of the legislation. Although courts generally have inferred authority to serve the above purposes, the doctrine of implied authority is not necessarily limited to these areas, especially in light of the evolving nature of the case law.

In conclusion, a decision to require health warning statements under the FAA Act should be legally sustainable, although not free from challenge.

II. AUTHORITY TO REGULATE PRODUCTS CONTAINING ALCOHOL UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Products containing alcohol that are "used for food or drink for man or other animals" are "food" within the meaning of 21 U.S.C. § 321(f). In addition, products containing alcohol may be drugs if they are intended for drug use. 21 U.S.C. § 321(g). It is a violation of the Federal Food, Drug, and Cosmetic Act (Act) to deal in interstate commerce with foods or drugs, including those containing alcohol, that are adulterated. See 21 U.S.C. §§ 321, 342, and 351.

The Act also prohibits dealing in interstate commerce with foods or drugs that are misbranded within the meaning of the Act. See 21 U.S.C. §§ 321, 343, and 352. A food or drug is misbranded if, among other things, its label is false or misleading in any particular. 21 U.S.C. §§ 343(a) and 352(a). A label is misleading if it should bear a health warning and does not under the Food and Drug Administration's interpretation of 21 U.S.C. § 321(n).

In addition, food labels must list the food's ingredients. 21 U.S.C. § 343(i). Drug labels must list all active ingredients, including alcohol. 21 U.S.C. § 352(e)(i).

While FDA administers the Act, the Department of Justice institutes, usually at FDA's request, seizure, injunction, and criminal actions to enforce the provisions described above. See 21 U.S.C. §§ 332, 333, and 334.

The decision of the district court in Brown-Forman Distillers Corp. v. Mathews, 435 F. Supp. 5 (W.D. Ky. 1976) effectively deprived FDA of any authority over the labeling of alcoholic beverages. The court held that the more specific labeling authority granted to the Bureau of Alcohol, Tobacco and Firearms by the Federal Alcohol Administration Act conflicted with the broader mandate of the Federal Food, Drug, and Cosmetic Act and that the former statute was controlling. The court held, therefore, that the Federal Food, Drug, and Cosmetic Act does not apply to the labeling of alcoholic beverages. This decision was not appealed by the Government and cannot now be appealed.

Because ATF and FDA have historically agreed that wines containing less than 7 percent alcohol are not alcoholic beverages regulated by ATF under its statute, FDA has continued to regulate the labels of those wines. The plaintiffs in the Brown-Forman suit, however, have recently challenged, in a contempt of court action, the FDA's practice of regulating the labeling of wines containing less than 7 percent alcohol. The district judge denied the contempt order sought. That denial is now on appeal. See Brown-Forman Distillers Corp. v. Harris, C 76-0042-0 (W.D. Ky. April 12, 1979), appeal pending, No. 79-3464 (6th Cir.).

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GLOSSARY

Definitions presented are based on the indicated sources except when amended to improve clarity.

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aberrant palmar creases
atypical creases in the palm of the hand (Stedman's)

acetaldehyde
a colorless liquid with a characteristic pungent odor (CH_3CHO), resulting from the metabolism of ethanol and producing profound necrosis and deleterious aftereffects (Dorland's, Gould)

acinar
minute, grape-shaped secretory portions of a gland (Stedman's)

acute
of a short and sharp course, not chronic (Stedman's)

aerodigestive
combined respiratory and digestive tracts

affective disorders
disturbance of mood, accompanied by a full or partial manic or depressive syndrome that is not due to any other physical or mental disorder; mood refers to a prolonged emotion that colors the whole psychic life (DSM-III)

alcoholic hyaline
Mallory bodies; large, poorly defined accumulations of eosinophilic material in the cytoplasm of damaged liver cells in certain forms of hepatitis, cirrhosis, and in conditions where marked fatty changes occur, especially due to alcoholism (Stedman's)

aldosterone
steroid hormone secreted by the adrenal cortex (Stedman's)

anomalies (plural of anomaly)
deviation from the average or norm; anything unusual, irregular, or contrary to a general rule (Stedman's)

anorexia
diminished appetite; aversion to food (Stedman's)

antagonistic
denoting mutual opposition in action between ... drugs (Stedman's)

antepartum
before labor or child birth (Stedman's)

asymptomatic
without symptoms, or producing no symptoms (Stedman's)

ataxia
a loss of muscular coordination (Stedman's)

ATP (adenosine triphosphate)
major carrier of chemical energy in cells of all living species

atrophic
a wasting of tissues (Stedman's)

axonal degeneration
deterioration of the essential conducting portion of a nerve fiber continuous with the cytoplasm of a nerve cell (Stedman's)

BAC (blood alcohol concentration)
grams of ethanol per 100 milliliters of blood, sometimes abbreviated as grams percent

beri-beri
a disease resulting mainly from a deficiency of thiamin in the diet (Stedman's)

birth defect
defect - imperfection; malformation (Stedman's)
any genetic or congenital imperfection or malformation

buccal
pertaining to, or adjacent to, the cheek (Stedman's)

carcinoma
any of the various types of malignant neoplasm (tumor) derived from epithelial (surface) tissue in several sites (Stedman's)

cardiomegaly
enlargement of the heart (Stedman's)

cardiomyopathy
disease of the heart muscle (Stedman's)

carnitine
a constituent of striated muscle and liver; Vitamin B_T (Gould)

cerebellum
posterior brain mass (Stedman's) which functions as a reflex center for the regulation of muscle tonus, for coordination of synergy of movements, and for balancing or equilibrium (Concise Anatomy)

chronic
of long duration; denoting a disease of slow progress and long continuance (Stedman's)

cirrhotics
(persons suffering from) a progressive and chronic disease of the liver characterized by diffuse damage to hepatic parenchymal cells, with nodular regeneration, fibrosis, and disturbance of normal architecture (cirrhosis) (Stedman's)

complement
substance in normal blood serum and plasma that in combination with antibodies causes the destruction of bacteria, foreign blood corpuscles, and other antigens and is very sensitive to heat (Webster's)

concomitant
accompanying (Webster's)

confabulation
making up of tales and recitals and a readiness to give a fluent answer, with no regard to facts, to any question asked (Stedman's)

demyelination
destruction or loss of the white, fatty substance (myelin) from the medullary sheath of Schwann (nerve sheath) cells (Stedman's)

depressed myocardial contractility
decrease in the ability of the heart muscle to shorten or contract

diaphoresis
perspiration, sweating (Stedman's)

diencephalon
that part of the brain which contains the thalami, controlling olfactory, visual, and other reflexes (Concise Anatomy)

diffuse fibrosis
widespread formation of fibrous tissue in an organ or tissue in which fibrous tissue is not a normal constituent (Stedman's)

disinhibition theory
a theory that alcohol acts to release normal inhibitory mechanisms, such that a behavior which would normally be repressed may be activated

distal portion
portion which is farthest from the trunk, referring to the segments of the extremities (Stedman's)

disulfiram
antioxidant compound used as an adjunct in the treatment of alcoholism (Modern Drug Encyclopedia)

dysmorphologist
physician who practices the sub-specialty of pediatrics concerned with birth defect

dyspnea
subjective difficulty or distress in breathing, frequently rapid breathing, usually associated with serious disease of the heart or lungs (Stedman's)

electroencephalography
registration of the electrical potentials of the brain recorded by an electro-encephalographic device (Stedman's)

embryotoxic
substance which is harmful to an embryo

encephalopathy
any disease of the brain (Stedman's)

epidemiology
science that deals with the incidence, prevalence, distribution, and control of disease in a population (Webster's)

erosive
having the property of wearing away (Stedman's)

esophageal
pertaining to the esophagus or musculomembranous passage extending from the pharynx to the stomach (Dorland's)

ethanol analogs
drugs such as paraldehyde and chloral hydrate (ref. 134)

etiology
causation; the doctrine of causes, the study of causes, specifically the cause of disease (Stedman's)

fibrosis
formation of fibrous tissue in an organ or tissue in which fibrous tissue is not a normal constituent (Stedman's)

first degree relatives of primary alcoholics
parents of alcoholics, with the latter having no affective disorder (ref. 302)

fulminant
running a speedy course, with rapid worsening (Stedman's)

gamete
any germ (i.e., sex) cell (Stedman's)

gastritis
inflammation of the stomach (Stedman's)

gastroduodenal ulceration
lesion at the junction of the stomach and intestine, the pylorus

gastroesophageal junction
junction point between the stomach and the esophagus

global confusion
state in which the person is totally bewildered, perplexed, or unable to orient (Stedman's)

habituation
the process by which the nervous system reduces or prevents responses to inconsequential repeated stimulation (Stedman's)

heavy drinkers
Researchers frequently classify heavy drinkers as those whose average daily consumption is more than 3 standard drinks (1.5 ounces of absolute alcohol). In addition, some researchers define heavy drinking on the basis of adverse biomedical and/or psychosocial consequences. Although no standard definition is currently available, researchers usually include a definition of heavy drinking when they report their findings.

hippocampus
elongated limbic structure composed of a modified type of cerebral cortex, the functions of which are little understood (Textbook of Medical Physiology)

hydronephrosis
enlargement of one or both kidneys resulting from obstruction to the flow of urine (Stedman's)

hyperhydrosis
excessive or profuse sweating (Stedman's)

hyperplasia
increase in number of cells in a tissue or organ...whereby the bulk of the part or organ is increased (Stedman's)

hypopharyngeal (see hypopharynx)

hypopharynx
that part of the pharynx (throat) lying below the upper edge of the epiglottis and opening into the larynx and esophagus (Dorland's)

hypothalamic-pituitary-adrenal axis
hormone vectoral transmission between the hypothalamus, pituitary gland, and adrenal glands

hypothalamic-pituitary-gonadal system
hormone vectoral system between the hypothalamus, pituitary, and gonads

hypotonia
condition in which there is a diminution or loss of muscle tonicity, in which the muscles may be stretched beyond their normal limits (Stedman's)

intestinal malabsorption
poor or inadequate absorption of nutrients and minerals through the intestinal membranes into the blood stream

intestinal motility
pertaining to the rhythmic peristaltic motion of the intestine

involutional melancholia (see late onset unipolar depression)

kcal (kilocalorie)
any one of several heat units that represent the quantity of heat required to raise the temperature of one kilogram of water one degree centigrade (Gould)

late onset unipolar depression
relatively late-in-life occurrence of one or more major depressive episodes without a history of a manic episode (DSM-III)

lipid
any one of a group of fats and fat-like substances having in common the property of insolubility in water and solubility in fat solvents (Gould)

lipid metabolism
chemical changes of oxidation, decomposition, and synthesis that fats undergo in tissues (Stedman's)

lipoprotein
complexes or compounds containing lipid and protein (Stedman's)

low mean cardiac output
decrease in the average amount of blood pumped by the heart (Stedman's)

lymphocyte
white blood cell formed in lymphoid tissue throughout the body (Stedman's)

manic depressive disease
includes manic episodes, major depression episodes, mixed bipolar disorder, manic bipolar disorder, and depressed bipolar disorder (DSM-III)

meconium
first intestinal discharges of the newborn infant, greenish in color, and consisting of epithelial cells, mucus, and bile (Stedman's)

medulla
lowest portion of the brain stem; continuous with the spinal cord; controls involuntary body functions such as breathing

microcephaly
abnormal smallness of the head (Stedman's)

microphthalmia
small eyes (Stedman's)

microsomal enzyme oxidizing system
putative pathway for the oxidation of ethanol to acetaldehyde, located in the smooth endoplasmic reticulum of the hepatocyte, which utilizes the cofactor NADPH as distinct from NAD^+ of the cytosolic enzyme alcohol dehydrogenase (ref. 102,122)

migration-inhibitory-factor (MIF)
substance released by peripheral-blood lymphocytes from patients with alcoholic hepatitis when exposed to purified alcoholic hyaline (ref. 153)

MMPI
Minnesota Multiphasic Personality Inventory (Dorland's)

morbidity
ratio of sick to well in a community (Stedman's)

morphologic
pertaining to the configuration or the structure of a person (Stedman's)

mucosal tear
a wound, rip, or laceration in any mucosal membrane

myocardium
heart muscle (Stedman's)

myoglobinuria
excretion of myoglobin (muscle protein) in the urine (Stedman's)

myopathy
any abnormal condition or disease of the muscular tissues (Stedman's)

necrosis
pathologic death of one or more cells, or of a portion of tissue or organ, resulting from irreversible damage (Stedman's)

neonatal apgar score
evaluation of a newborn infant's physical status by assigning numerical values to the heart rate, respiratory effort, muscle tone, reflex irritability, and skin color (maximum score is 10) (Stedman's)

neonate
pertaining to an infant in the period immediately succeeding birth through the first month of life (Stedman's)

neonatologist
a pediatrician specializing in clinical service to neonates (Stedman's)

neoplasm
abnormal tissue that grows by cellular proliferation more rapidly than normal (Stedman's)

neoplastic (see neoplasm)

neuropathological
relating to diseases of the nervous system (Stedman's)

neuropathy
functional disturbances and/or pathological changes in the peripheral nervous system (Dorland's)

neuropsychology
study and measurement of mental functions (Stedman's)

neurotoxic
poisonous to nervous tissue (Stedman's)

nodular
pertaining to, or consisting of, a circumscribed mass (Webster's) of tissue

nystagmus
rhythmical oscillation of the eyeballs, either horizontal, rotary, or vertical (Stedman's)

ophthalmoplegia
paralysis of one or more of the motor nerves of the eye (Stedman's)

oropharyngeal (see oropharynx)

oropharynx
part of the pharynx (throat) that lies posterior to the mouth (Stedman's)

palpate
to examine by feeling and pressing with palms and fingers (Stedman's)

palpebral fissures
slit or fissure between the opposed lids of the closed eye (Stedman's)

pancreatitis
disease of the pancreas with inflammation of pancreatic tissue (Dorland's)

parity
state of a woman as regards to having children; nulliparity - having had no children, primiparity - having borne one child, etc. (Stedman's)

peripheral blood
blood taken from the small blood vessels of the extremities

peripheral neuropathy
disease of the peripheral nerves as contrasted to those of the central nervous system (Dorland's)

peristaltic
wave of alternate circular contraction and relaxation of intestines and esophagus, by which the contents are propelled onward (Stedman's)

phagocytosis
process of ingestion and digestion by specific cells of bacteria, bits of dead tissue, foreign particles, and other cells (Stedman's); usually refers to ingestion by white blood cells

pharmacokinetic - pharmacodynamics
study of the actions of drugs on the living organism (Stedman's)

physiologic
pertaining to the science of living...processes (Stedman's)

pneumoencephalography
radiographic visualization of cerebral ventricles and subarachnoid spaces by use of a gas such as air or oxygen (Stedman's)

polyneuropathy
disease process involving a number of peripheral nerves (Stedman's)

postmenopausal amenorrhea
cessation of menstruation as after the menopause (Dorland's)

premorbid cognitive state
state of mental functions prior to the onset of a disease

prospective
concerned with or relating to the future (Webster's); in epidemiology, a survey which is initiated prior to the occurrence of the event which is to be studied

prospective cohort study
a study in which risk information is collected prospectively for an entire patient population sample but in which the selection of outcome measures for analysis is made after completion of data collection (Rogan and Brown, 1979)

prothrombin
a glycoprotein which is formed and stored in the parenchymal cells of the liver; it is present in blood (In the presence of thromboplastin and calcium ion, prothrombin is supposedly converted to thrombin, which in turn converts fibrinogen to fibrin; the process resulting in coagulation of the blood.) (Stedman's)

proximal
nearest the trunk or point of origin; used to identify part of a limb, artery, or a nerve, etc., so situated (Stedman's)

proximal myopathy
disease of muscles close to the trunk

pseudo-Cushing's Syndrome
condition of excess adrenal cortisol and glucose in the blood of nursing babies which causes paunchiness and "balloon face" (ref. 20)

psychomotor
relationship of the mental origin of muscular movements to the production of voluntary movements (Stedman's)

retrospective
act or process of surveying the past (Stedman's)

salicylates
class of drugs of which aspirin is a member (Modern Drug Encyclopedia)

seizurogenic
that which causes or produces seizures or convulsions

self-reporting
as reported by the subject

sensorium
consciousness (Stedman's)

sequelae
pertaining to the Nature of a morbid condition resulting from a disease (Stedman's)

sober alcoholic
alcoholics who have no measurable level of alcohol in their body; this term is often used to describe detoxified alcoholics

sociopathy
condition affecting a person with a pathological attitude toward society (Dorland's)

sphincter
muscle that encircles a duct, tube, or orifice in such a way that its contraction constricts the lumen or orifice (Stedman's)

spina bifida
a limited defect in the spinal column, consisting of absence of the vertebral arches through which the spinal membranes, with or without spinal cord tissue, may protrude (Stedman's)

systematic naturalistic observations
organized procedure for the observation and recording of the natural behavior of a subject; for example, sleeping, yawning, staring, etc. (ref. 148)

temporal cortex
surface layer of the temporal lobe of the brain

teratogenic
dealing with the production, development, and anatomy of birth defects (Stedman's)

thymus
lymphoid organ located in the superior mediastinum and the lower part of the neck (Stedman's)

tomography
method of taking sectional x-ray pictures (Stedman's)

ultrastructure
arrangement of ultramicroscopic particles (Gould)

varice
enlarged and tortuous vein, artery, or lymphatic vessel (Stedman's)

warfarin-type of anticoagulant
synthetic coumarin drug that depresses the formation of prothrombin in the liver, and interferes with the production of factors VII, IX, and X, thereby minimizing intravascular clotting (Modern Drug Encyclopedia)

Zung Depression Scale
self-rating depression scale for the quantitative measurement of depression (Zung, 1965)

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